REPORT TO THE COMMISSIONER: ACTIVITIES OF THE VIRGINIA DEPARTMENT OF HEALTH INSTITUTIONAL REVIEW BOARD CALENDAR YEAR 2014

DRAFT

Submitted by

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Chair
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REPORT TO THE COMMISSIONER:
ACTIVITIES OF THE VDH IRB FOR CALENDAR YEAR 2014

Regulations for the conduct of human research, developed and approved by the Virginia Board of Health, became effective on July 1, 1993. 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".

Dev Nair, PhD, MPH, 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.

The following is a summary of the activities and actions of the VDH IRB as per state "Regulations for the Conduct of Human Research" (12 VAC 5-20-50) during calendar year 2014.

Review Type	Approved	Not Approved	No Action
Full Review	0	0	0
Expedited Review	17	0	1
Exempt Review	24	0	0

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

A. Full Board Reviews
None

B. Expedited Reviews:

Study#: 40187
Title of Study: Mother and Infant Home Visiting Program Evaluation-Strong Start (MIHOPE-SS)
Principal Investigator: Charles Michalopoulos, PhD
Date Approved: January 28, 2014
Description of Study: The purpose of MIHOPE-SS is to evaluate the effectiveness to two home visiting models-Healthy Families America (HFA) and Nurse Family Partnership (NFP) on birth outcomes and infant health for women who are enrolled in Medicaid or the Children's Health Insurance Program (CHIP) and who are no more than 32 weeks pregnant when they enter the study. MIHOPE-SS is part of an ongoing research agenda to inform policymakers about whether home visiting programs are achieving their expected effects, which can affect future funding for the programs. MIHOPE-SS will also provide information to help programs operators strengthen future programs to increase their effectiveness for families. Research activities such as surveys will include some sensitive questions. Individuals can refuse to answer the survey or any questions that cause discomfort, and interviewers will be trained to be sensitive to respondent's concerns. Subjects may disclose information during surveys that researcher are required to report. If the Principal Investigator learns of a situation that might require reporting (such as potential child abuse or neglect, or endangerment to others or to the study participant), they would consult with MDRC's legal counsel and together they would determine whether the incident requires reporting, and if so, to whom. All security policies, procedures and technical safeguards are consistent with the Privacy Act, the Health Insurance Portability and Accountability Act. Identifiable data will be encrypted at all times and passwords will be required for access. Identifiable data will be destroyed at the end of the study. All methods of destroying sensitive data are government approved.

Description of Action: Approved.

Study#: 40188
Title of Study: The Geographic Distribution and Risk Factors of Hepatitis C in the Pittsylvania-Danville Health District
Principal Investigator: Susan Marmagas, MPH
Date Approved: February 6, 2014
Description of Study: The goal of the study is to identify and quantify the risk factors for Hepatitis C in the Pittsylvania-Danville Health District in Virginia. The distribution of this disease will be mapped to identify "hotspots" associated with specific risk factors. This data will help improve the Virginia Department of Health's understanding of the disease in the area, and will help inform future interventions aimed at reducing the disease burden. The subject pool will include all cases of Hepatitis C within the last five years. Subjects will be contacted via telephone through the Virginia Department of Health (VDH) by VDH officials and asked if they would be willing to answer several question about their personal history in an effort to assist researchers tracking disease transmission in the Danville-Pittsylvania County area. Verbal consent will be obtained and the interviewer will explain how data are sanitized to protect anonymity and that their participation is voluntary. After the interview, participants will be asked if they wish to receive general counseling and/or general treatment recommendations. There are no physical risks. VDH data contains the personally identifying information; random numbers will be assigned to each case and will not include any personal identifying information. Files will be destroyed once data collection is complete. The analysis may be submitted for publication in a public health related journal and the research will be publicly presented at an end of year symposium by a Virginia Tech MPH Capstone student. The data will be provided to Virginia Department of Health for internal use.
Description of Action: Approved.

Study#: 40189
Title of Study: Behavioral Intervention to Reduce Breast Cancer Disparity in Underserved Koreans
Principal Investigator: Sunmin Lee, ScD
Date Approved: NA
Description of Study: The purpose of the study is to evaluate the effectiveness of an intervention program for underserved Korean American breast cancer survivors. A control and an intervention group will received educational sessions and the intervention group will receive sessions on enhancing coping. Telephone interviews will be conducted at three months, and pen and pencil questionnaires will be administered at other times. The research was originally approved by the University of Maryland School of Public Health IRB. The PI requests that the Virginia Cancer Registry (VCR) identify potentially eligible subjects and either provide the identifying data to them or VCR mail a letter directly to the potential participants.
Description of Action: After consulting with the Director of the Virginia Cancer Registry, no IRB action was taken on this proposal. Releasing the names and contact information for individuals contained in the Virginia Cancer Registry for the purpose of recruiting subjects for research is not an allowable use of Cancer Registry data at this time.

Study#: 40190
Title of Study: Herpes Simplex Virus **(**HSV) Prevalence and Education Study
Principal Investigator: Andrea S. Bertke, PhD
Date Approved: February 26, 2014
Description of Study: The study will provide preliminary data to support a federal grant proposal seeking funding for a long-term study that includes prevalence surveillance and development of education approaches that will reduce transmission and prevalence of genital HSV. Because HSV is not a disease reported to the health department, there is limited data on the rate of HSV in the US, particularly in rural areas. The goals of this study are to generate clear data on the frequency of HSV1 and HSV2 in high school and college-age individuals in a rural area; understand how people learn about HSV and sexually transmitted infections in general; investigate better approaches for teaching high school and college students about HSV and other sexually transmitted infections to ultimately reduce transmission rate among young people. This study will include a minimum of 200 participants between the ages of 14 and 25 who are in high school or college. Participants' recruitment includes advertising through the VT Daily News, class listservs, Blacksburg HS listserv, flyers, word of mouth and posting notices at various locations on college campus and high schools. Parental consent required for those under 18 years of age. The study will consist of two groups; blood draws and interview participants. The identified risk for blood draw may include a slight risk of excessive bleeding, fainting, feeling light-headed, hematoma, infection (a slight risk anytime skin is broken) and emotional risk. The principal investigator has taken appropriate measures to mitigate these risks and disclosed them on the parental and participant consent. Appropriate measures are taken to secure confidentially and allow subject privacy. Study data will be stored in a locked filing cabinet until the completion of the study with limited access only available to the researcher. The Principal Investigator is aware of the Virginia Department of Health policy regarding minors and sexually transmitted infections (STIs) and high risk sexual behavior topics.
Description of Action: Approved

Study#: 40191
Title of Study: Identifying Risk and Protective Factors for Developing Fungal Meningitis in the New River Valley
Principal Investigator: Caitlin Rivers, MPH
Date Approved: February 27, 2014
Description of Study: The study includes a review of medical records of clients who have received contaminated Epidural Spinal Injections (ESI). This will be an investigation of the variations of procedures used to administer the ESI which could have potentially been a factor in the development of fungal meningitis. The study population are 27 patients in the New River Valley that received the injection in 2012. Access to medical records of clients will be obtained through Virginia Department of Health (VDH). Data will be obtained through the records from charts that meet the study criteria; no other research use of other data/information in the records will be allowed. No data will be published or released in any form if a particular individual supplying the information or described in it is identifiable without the written permission of the subject(s) involved. The identifying information will be used only

for statistical purposes in medical and health research. Medical records and the linked code with identifying information will be stored in accordance with the VDH policy.
Description of Action: Approved.

Study#: 40192 (A)
Title of Study: Computerized Anonymous Health Survey: Richmond City Health Department
Principal Investigator: Dace S. Svikis, PhD
Date Approved: April 15, 2014
Description of Study: The goal of this study is to survey participants in the Richmond City Health Department's sexually transmitted infection (STI) clinics to gain a better understanding of substance use patterns and identify mental health and other general health related issues among clients seek STI services. The anonymous survey data will then inform subsequent program development. The computerized survey will be administered to adult STI client participants. An informed consent form will be available on the computer. Participants must be 18 years or older, be able to understand and read English and not show any signs of psychotic symptoms, delirium, recent drug use, etc. Participants will be told that the survey is anonymous and that no identifying information will be collected. Staff will be available to answer questions and ensure that adequate consent is obtained. The data will be housed with the Principal Investigator and analyzed to provide descriptive statistics regarding substance use, mental health issues and other medical conditions among individuals treated at the STI clinic. The study has minimal risk to participants. The study has been approved by the Virginia Commonwealth University IRB.
Description of Action: Approved.

Two Unanticipated Events related to this study occurred on the first day of the computer-directed survey administration (6/23/2014). The events were reported to the IRB. The first event was an error in the computer program regarding the informed consent process. The program allowed the participant to continue on to the survey without adequately completing the quiz relating to their understanding of informed consent. This was corrected by revising the verbal consent quiz programming and algorithm. The second event related to the computer-directed questions on recent suicide ideation. Instructions for the participants asked that they raise their hand for the assistance from the Evaluation Assistant if they answered that they had recent suicide thoughts. Two participants answered positively to the question however they did not contact the Evaluation Assistant and the computer program allowed they to click 'next" and continue with the survey. This was corrected by removing the "recent suicide question." In its place, at the end of the mental health survey section, all participants will receive the following message, "Thank you for answering our question! Your health is very important to us. If you would like information on mental health services or other resources, please see the evaluation assistant." All staff will be retrained on the new procedures and will monitor future enrollees on a case by case basis. Data will be reviewed daily to make sure that the new procedures are working properly.

Study#: 40193
Title of Study: Appalachian Access to Reproductive Health

Principal Investigator: Susan Marmagas, MPH

Date Approved: April 30, 2014
Description of Study: The purpose of this study to identify barriers and facilitators of reproductive aged women seeking care for reproductive health, to assess women's perception of their reproductive health care needs and to determine women's sources of reproductive health care information. This multi-state study includes three groups of women aged 16 – 45 years old who are either presently accessing specialized reproductive health services, who are presently accessing general reproductive health services, or who are not presently accessing any reproductive health services. The proposed study is a qualitative research design, using semi-structured interviews. The informed consent is adequately detailed and will be stored separately from the completed interview material. No identifying information will be included in any recordings or transcripts. Measures to protect the confidentiality are provided. The study presents minimal risk to participants. Participants completing the interview will receive a gift card. The study has been approved by the Harvard University IRB and approval from the Kentucky Department of Health IRB is pending.
Description of Action: Approved.

Study #: 40194
Title of Study: An Evaluation of the Necessity for Colonoscopy following an initial Episode of Acute Diverticulitis
Principal Investigator: Richard Bloomfield, MD
Date Approved: August 14, 2014
Description of Study: The purpose of this retrospective cohort study is to compare the incidence of advanced adenomas detected on colonoscopy in the study to the control groups. Cases will be matched to controls using age, gender and race. The study population is patients at the Wake Forest Baptist Hospital who developed acute diverticulitis between the years 2000 and 2011. The Virginia Cancer Registry will provide information on any of the Wake Forest patients who were later diagnosed with any type of malignancy. The risk to study patients is small however includes the potential risk of leakage of identifiable information. The confidentiality will be protected by minimizing the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. Only a unique study identifier will appear on the data collection form. The unique identifier will be maintained on a linkage file and stored separately from the data. Following data collection, subject-identifying information will be destroyed. No reference to individual subjects will appear in reports or presentations.
Description of Action: Approved

Study#: 40195
Title of Study: National Association of State Public Health Veterinarians: Veterinary Information Network (VIN)
Principal Investigator: Tracy Witt, PhD
Date Approved: June 18, 2014
Description of Study: The goal of this multi-state study is to assess serious mental illness among veterinarians using an anonymous, electronic survey. The survey will be used to determine an estimate of the proportion of US veterinarians who recently

experienced a mental illness or contemplated suicide; measure the perceived stigma among veterinarians related to mental illness; measure the perceived access to mental health treatment; and measure the perceived stressors related to veterinary practice. The survey data will be collected anonymously with no direct or indirect coding, link or awareness of who participated in the study and will be stored securely on Auburn University's password protected server and is only accessible by the study's principal investigator. The proposed study has been reviewed and approved by the Auburn University IRB.
Description of Action: Approved

Study#: 40196
Title of Study: Special Projects of National Significances-Systems Linkages and Access to Care Initiatives: Qualitative Client Interviews at Virginia Commonwealth University
Principal Investigator: Anne Rhodes, MPH
Date Approved: June 18, 2014
Description of Study: The purpose of this multi-state study is to evaluate interventions to increase linkage and retention in HIV care. The study will involve conducting interviews with patients'/clients who have been exposed to the patient navigation intervention at the Virginia Commonwealth University Health Services (VCUHS). Interviews will be conducted by staff from the University of California at San Francisco' Evaluation and Technical Assistance Center and VDH staff. Informed consent will be obtained from all participants prior to the interview and each will be provided with an information sheet summarizing the purpose of the study and their involvement. Following the interview the participants will be provided with a gift card and a gas card. Appropriate measures are taken to secure confidentiality and allow subject privacy. No patient identifiers will be stored with the research records. The Virginia Commonwealth University IRB and the University of California at San Francisco are also reviewing this proposed study.
Description of Action: Approved.

Study#: 40197
Title of Study: 2014 Virginia Adult Dental Access Survey
Principal Investigator: Anne Zehner
Date Approved: June 25, 2014
Description of Study: The purpose of this study is to determine factors related to dental care access for adults in Virginia. A questionnaire containing approximately 25 questions will be administered in both English and Spanish (as necessary) by telephone to Virginia adults. 2500 completions have been estimated as an adequate sample to obtain data from the five health planning regions. Both landline and wireless numbers will be included. Informed consent will be obtained verbally. No identifying information will be collected and phone numbers of respondents will not be stored with the data collected. The Center for survey Research – UVA server will be used to store aggregate data and analysis. Any risk to participants is minimal.
Description of Action: Approved.

Study#: 40198
Title of Study: 2014 Virginia Statewide Oral Health Assessment
Principal Investigator: Karen C. Day, DDS, MPH
Date Approved: July 1, 2014
Description of Study: The purpose of this study is to conduct an assessment of the oral health of 3rd grade children in Virginia. A representative sample of Virginia's public elementary schools will be secured and parental consent forms will be distributed to all 3rd grade children within the selected schools. Participating children will be screened by VDH Dental Program providers and parents will be provided with a summary of their child's screen. Summary results of the needs assessment will be shared with the Department of Education and others at their request. Each child will receive a unique identifier so that no names will be entered into the database. Any risk to participants is minimal. Similar surveys were approved by the VDH IRB in 2009 and 2012.
Description of Action: Approved.

Study #: 40199
Title of Study: Pregnancy and Childbirth within the Context of Incarceration
Principal Investigator: Danielle H. Dallaire, PhD
Date Approved: July 15, 2014
Description of Study: The purpose of this study is to use secondary Pregnancy Risk Assessment Monitoring System (PRAMS) to assist in examining the needs of incarcerated pregnant women compared to the general population. The state VA PRAMS data will be merged with the previously collected data from incarcerated women in order to make comparisons on several variables across the two groups. All databases have been de-identified. However, since there are a small number of women in the study there may be a risk of potential identification of the women.
Description of Action: Approved

Study #: 40200
Title of Study: The Geographic Distribution and Risk Factors of Hepatitis C in the New River Valley
Principal Investigator: Kaja M. Abbas, PhD, MPH
Date Approved: July 30, 2014
Description of Study: The purpose of this case-control study is to identify and quantify the risk factors of Hepatitis C in Southwest Virginia. The study population consists of the Hepatitis C cases reported to the New River Valley Health District during the last five years. The control group will be recruited via social-media (post requesting folks to take the survey) and by email sent to the MPH list-serve and by paper survey left with cooperating healthcare facilities in the area. No personal identifying information will be recorded. This study was approved by Virginia Tech's IRB.
Description of Action: Approved

Study #: 40201
Title of Study: North American Wilms Tumor Study

Principal Investigator: Rayjean Hung, PhD, MS
Date Approved: August 5, 2014
Description of Study: This is a comprehensive study to investigate the effect of genetic and reproductive factors and gene-environment interaction on the risk of Wilms tumor. Wilms tumor is a childhood disease, however the parents of both the cases and controls are asked to participate on behalf of the child. All questionnaires are administered to the parents/guardians. The control children are asked to submit a saliva sample if parents consent to it. Children over the age of seven are provided an assent form. The study group will be recruited through the Childhood Cancer Research Network and include those who have provided consent for future contact. The control group will be randomly selected from the birth registry that matches age, sex, ethnicity and residence area of the cases. Information from both cases and controls will be collected by way of telephone interviews. Parents will be requested to submit saliva specimens and will be asked if they are willing to provide medical records of their children. A separate Health Insurance Portability and Accountability Act (HIPAA) consent form will be provided. Study forms containing protected health information will be encrypted and personal identifiers will be stored in locked file cabinets. Biospecimens will be labeled with participant number. Only the principal investigator and study coordinators will have access to information linking personal identifiers to health information.
Description of Action: Approved

Study #: 40202
Title of Study: Head Start Dental Basic Screening Survey
Principal Investigator: Susan Pharr
Date Approved: September 24, 2014
Description of Study: This study will document the oral health status of the high-risk child population and determine the treatment needs and risk of future disease. The information will be used to determine prevention needs of the children and the education needs of parents. The study findings will also help determine workforce and policy changes needed to reduce dental disease rates in low income pre-school children. All children ages three to five enrolled in Virginia's Head Start programs are required to have a dental exam by a dentist within 90 days of enrollment. About 70% of the centers currently utilize an existing software program "Child Plus" to store the health data of the children. The dental assessment of each child will be included in this system and will be provided to VDH via a password protected CD which will not contain the names of students. The remainder of the centers will provide the paper form completed for each child to VDH via secure mail. Each child will be given an unique identifier as the data are entered. The CD and paper forms will be destroyed once data has been cleaned, analyzed and reported. An informed consent form indicates that information will be shared with the Virginia Department of Health and that participation is voluntary.
Description of Action: Approved

Study#: 40203
Title of Study: Pertussis and Health Beliefs
Principal Investigator: Bernice Hausman, PhD
Date Approved: October 29, 2014
Description of Study: In Spring 2011, a pertussis (whooping cough) outbreak

occurred at a private school and its affiliated daycare in Virginia; a second outbreak occurred at the same school. This study is to investigate the relationship between the health department and the affected community. The research is being conducted by researchers from Virginia Tech and George Mason universities. Researchers believe more qualitative research is needed to begin to understand the complexities in these interactions. The research will be conducted in two stages: stage one, seeks to understand the perspective of the local public health workers and to establish their view of their role in containing an outbreak, their understanding of the affected families' behaviors and their perception of the obstacles to establishing a trusting relationship between the health department and the community. Stage two seeks to understand the perspective of local health care providers in the local community; the parents of affected and non-affected children. You must be at least 18 years of age to participate in this study. All interviews will be audio recorded; written, verbal consent will be obtained and documented; each signed consent form will have a code number. Tapes and transcripts will be referred to by the code number. Data will be kept in locked file cabinets and audio files will be saved on an external hard drive; erased off the computer with password protection. Data will be archived and retained for the duration of the study; then erased when no longer utilized. Study results may be published in refereed, scholarly journals; possibly published as part of a dissertation; and will be provided to the local health department in a report with feedback to help improve communication with the community. Copies will be provided to members of the community by request.

Description of Action: Approved

C. Exempted Reviews

Study#: 50153
Title of Study: Distribution of Wildlife Rabies and Analysis of Factors Influencing Human Exposure in Central Appalachia
Principal Investigator: Wayne Sanderson, PhD, CIH
Date Approved: January 15, 2014
Description of Study: The purpose of this study is to determine the factors that may influence the rate of exposure to rabies in Appalachia (Kentucky, Virginia, West Virginia and North Carolina) and to document trends in the distribution of rabies in wildlife across the region. US Census data to calculate socio-economic status and population size of participating counties will be used to analyze human factors that may influence rabies exposure. A spatial analysis of the distribution of human and wildlife rabies in the region will be performed using geographic information system (GIS) mapping and rabies reports. Researchers will be measuring the rate of positive rabies exposure per health region. All data will come from state tests results of submitted animals and does not confirm whether or not any individual actually has rabies. No human subjects are involved in the study. The data cannot be traced to any individual subject.
Description of Action: Approved

Study#: 50156
Title of Study: Impact of State-Funded Prenatal Program on Birth Outcomes in the New River Health District: A

Retrospective Analysis from 2010-2012
Principal Investigator: Sonia M. Vishneski, WHNP-BC, DNP
Date Approved: January 24, 2014
Description of Study: The purpose of the study is to describe the relationship of the state-funded prenatal program on the birth outcomes in the New River Health District of those enrolled in the state-funded prenatal program and those not enrolled in the program. This is a multiphase, retrospective longitudinal study using a descriptive and correlational design. Descriptive statistics will be used to describe the characteristics of the maternal patients in the study. Correlational and regression analysis will be used to examine the relationship between the independent and dependent variable of the study. The study population includes women enrolled and not enrolled in the state funded prenatal program over the past three years at the health department. Data from patient charts and birth certificate reports from Giles, Floyd, Montgomery, Pulaski and Radford County from 2010-2012 will be analyzed. Patient confidentiality will be protected during the process and each subject will be assigned an anonymous identification number. This study will provide a better understanding of the impact of the prenatal programs on birth outcomes in the community and this region of the state.
Description of Action: Approved

Study#: 50157
Title of Study: Knowledge, Perceptions & Awareness of Rabies and Cost-Analysis of Rabies Investigations
Principal Investigator: Kerry Redican, PhD
Date Approved: February 6, 2014
Description of Study: The purpose of the study is to learn about the epidemiology of rabies, including the associated cost for medical intervention and risk factors associated with exposure to rabies. The researcher plans to accomplish the following: characterize rabies in New River Health District (NRHD) related to person, place and time; conduct a cost analysis for rabies investigations (post-exposure prophylaxis); and conduct a community health needs assessment to identify risk factors for rabies exposure. The subjects in this study will be over 18 years with potential rabies exposure in NRHD including counties Floyd, Pearisburg, Montgomery, Pulaski and Radford. The identified persons will be contacted and asked to complete a survey; their responses will be anonymous. Consent will be implied by completion and return of the questionnaire. The survey will include an explanation of the study and statement regarding informed consent. The study files will not contain identifying information. The study protocol includes an adequate data security plan.
Description of Action: Approved

Study#: 50158
Title of Study: Remote Patient Monitoring (RPM) for Chronic Disease
Principal Investigator: Nancy Welch, MD, MHA, MBA
Date Approved: February 6, 2014
Description of Study: The purpose of the study is to determine the effectiveness of a Remote Patient Monitoring (RPM) program for at risk patients with diabetes, hypertension and heart disease who are cared for by Main Street Physicians (MSP). The service is a collaborative effort of Main Street Physicians and the Western Tidewater Health District (WTHD). The study population is adult patients (ages 21-80 years) who

have had at least three ER/hospital visits in the last 12 months and who have a documented diagnosis of Type 2 diabetes, hypertension and/or heart disease. Any patient with a terminal illness or disease will be excluded from the study. Eligible patients will be identified through a medical record review. Eastern Virginia Medical School will receive de-identified data for the analysis. Data will reside on an internal server shared secured by group policies limiting access to only authorized users. Study findings will be shared with the Virginia Department of Health and may be published in a national nursing or public health journal. No identifying information will be included in the final analysis.
Description of Action: Approved

Study#: 50159
Title of Study: Influenza Vaccination Study
Principal Investigator: Randle D. Raggio, PhD
Date Approved: February 21, 2014
Description of Study: This study will examine individual attitudes and behaviors related to the influenza (flu) vaccination. The information obtained will be used to help create a marketing plan for the Virginia Department of Health. This is a class project conducted by the students in the Marketing class at the University of Richmond (UR). The study population is students enrolled at UR who are 18 years or older and voluntarily answer a survey regarding their attitudes and behaviors related to the flu vaccination. The online survey includes information regarding informed consent. There will be no attempt to contact participants following the completion of the survey. No personally identifiable information will be collected.
Description of Action: Approved

Study #: 50160
Title of Study: Priorities in Rural Health: Cost effectiveness, Analysis of Fungal Meningitis Outbreak in New River Health District
Principal Investigator: Kaja Abbas, MS, PhD, MPH
Date Approved: March 12, 2014
Description of Study: The purpose of this study is to develop a decision analytic model to analyze fungal meningitis outbreak investigations in New River Health District (NRHD), incorporating cost and effectiveness. Non-identifying data of patients who were at risk of developing fungal meningitis due to receiving contaminated injection have been gathered from NRHD will be analyzed and used to develop the model. The findings from this study will serve as preliminary results for a proposal to be submitted to the National Institutes of Health. The secondary database containing de-identified information will be housed by the researcher at the New River Health District. The study poses minimal risk for patients.
Description of Action: Approved

Study #: 50161
Title of Study: Impact of Race and Socioeconomic Status on Breast Tumor Characteristics in Virginia
Principal Investigator: Luisel J. Ricks-Santi, PhD
Date Approved: March 14, 2014
Description of Study: The study will analyze the characteristics of breast cancer

in Virginia and determine how race, socioeconomic status and geography impact breast cancer characteristics. The study population will include all histological confirmed malignant breast cancer in Virginia diagnosed between 2000-2013. De-identified data will be analyzed for association between race/ethnicity and geography with cancer stage, grade, hormonal status, molecular subtype and survival status. This study will be based on data from the Virginia Cancer Registry (VCR). The researcher has signed the VCR data recipient agreement and VDH's assurance of confidentiality. All data shared by the VCR will be kept in a password protected computer only accessible by the principal investigator. No name or personal identifiers are being requested and analyses will be reported in aggregate form.
Description of Action: Approved

Study#: 50162
Title of Study: Southeastern States Occupational Network (SouthON) Occupational Heat-related Illness Study
Principal Investigator: Laurel Harduar Morano, PhD, MPH
Date Approved: March 27, 2014
Description of Study: SouthON is a collaboration with state health departments in the southeast (Arkansas, Georgia, Florida, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, West Virginia and Virginia). The study is a descriptive analysis reviewing hospital discharge data for all identified occupational heat-related illness hospitalizations in selected states in the southeast U.S for the period of 2007-2011. The baseline data will be used to inform policy and support the implementation/evaluation of prevention measures. The Emergency Department data file will include all records where the patient was seen in the emergency department and released; files exclude patients who were subsequently admitted to the hospital. All data will be de-identified and presented only in aggregate form in pre-formatted tables.
Description of Action: Approved

Study#: 50163
Title of Study: Alcohol and Other Drugs Indicator Project
Principal Investigator: Thomas Largo, MPH
Date Approved: April 22, 2014
Description of Study: The purpose of this study is to determine the frequency and rate of hospitalizations attributable to alcohol and other drugs among states involved in the study. The methodology for calculating cases and case rates was recently developed by the Alcohol and Other Drugs Indicator workgroup of Council of State and Territorial Epidemiologists (CSTE). The study is intended to pilot the new methodology so that standardization of drug and alcohol reporting can occur across state lines. The study involves analysis of de-identified, secondary data sources and includes data from California, New Mexico, Florida, Michigan, Washington, North Carolina, Oregon, Kansas and Virginia. Data will be stored on secure servers with secure access protocols. This minimal risk study qualifies for exempt status.
Description of Action: Approved

Study#: 50164
Title of Study: Correlation of Clinical Data with Genotypes and Phenotypes of B Pertussis Isolates

Principal Investigator: Joshua Eby, MD
Date Approved: May 22, 2014
Description of Study: The purpose of this project is to evaluate genome evolution of the bacteria from specimens and patient data already collected from cases identified by the Virginia Department of Health during outbreaks over the last 10 years to determine if genetic evolution of bacterium to vaccines components may account for the waning efficacy of the vaccine. The provisions to protect the privacy of subjects and confidentiality of data are satisfactory. Access to data will be available through a code used by the researcher only. Patient data will be de-identified. A coded research data/specimens agreement has been signed by VDH and UVA investigators. The project has been reviewed and approved by the UVA IRB.
Description of Action: Approved

Study#: 50165
Title of Study: Ascertaining Dates of Death for Patients who used VCU Health System for Disease Registries and Monitoring Mortality Rates and Other Quality Metrics
Principal Investigator: J. Brian Cassel, PhD
Date Approved: May 29, 2014
Description of Study: The purpose of this study is to identify VCU Health System (VCUHS) patients who are now known to be deceased in order to evaluate the effectiveness of the palliative care and advanced illness management efforts and to ensure that the various disease registries have accurate information on deaths. Currently decedents are identified through hospital deaths and the purchase of the Social Security Death Index (DMF) and its monthly updates. The proposed study will match Virginia Vital Records death data with their patient records to identify patients who are now known to be deceased and the date of death. The access to current death data is limited to identifying patients dying in the hospital and the Death Master File from Social Security however a minority of deaths occur in hospitals and since 2011 the DMF has been censored by approximately 40% of its records. The study only includes deceased individuals and patient PHI will only be used to ensure a correct match. The Principal Investigator was advised to contact the Virginia Department of Health's Office of Vital Records to complete a Data Use Agreement and to make arrangements to receive the data by a secure method.
Description of Action: Approved

Study#: 50166
Title of Study: Environmental Effects on Lyme Disease Transmission in Virginia
Principal Investigator: Tam Tran, MA
Date Approved: June 18, 2014
Description of Study: The goal of this vector-borne and zoonotic disease study is to confirm whether a relationship between environmental factors and the geographic incidence of Lyme disease exists in Virginia and how changes to the environment may influence Lyme outbreaks. The incidence rate of Lyme disease will be correlated to the environmental variables, both spatially and temporally on a geographical map and graphs. All individual identifying information will be removed so that anonymity will be preserved. No individual data will be provided in any publications, presentations or

posters; only the products of the data analysis will be presented.
Description of Action: Unanimously Approved.

Title#: 50167
Title of Study: Mental Health Conditions among State Quitline Callers: Utilization, Program Engagement and Outcomes
Principal Investigator: Katrina Vickerman, PhD
Date Approved: June 24, 2014
Description of Study This is a multi-state study to determine the prevalence of mental health conditions among Quitline callers and examine the demographic, tobacco history, treatment engagement and utilization of nicotine replacement therapy (NRT) for callers with vs. without reported mental health conditions. In addition a subset of the caller population will be selected for follow-up to determine seven month outcomes for callers with vs. without reported mental health conditions. The analysis will focus on previously collected data and will not involve any additional data collection or interaction with human subjects. No identifiable data will be shared outside of the Alere evaluation team. Analysis will be discussed with co-authors at the Centers for Disease Control and Prevention (CDC), but no raw data will be shared with CDC. All data, including registration and follow-up survey data are stored on secure database servers and can only be accessed by database administrators and evaluation staff. There are no potential risks to Quitline participants.
Description of Action: Approved

Title #: 50168
Title of Study: BRFSS Analysis for Partnership for People with Disabilities at Virginia Commonwealth University
Principal Investigator: Donna Giles, EdD
Date Approved: June 26, 2014
Description of Study: This is descriptive study to analyze the Behavior Risk Factor Surveillance Survey (BRFSS) including questions related to disability, activity limitations and need for assistance to 1) assess disability and health priorities for research, advocacy, and program development and 2) address disability disparity issues and advocate for pertinent disability and health needs through statewide collaborative relationships and 3) substantiate needs when developing proposals and funding requests. The analysis will also be used to update the previous Partnership report *Health Status of Virginians and Disabilities 2007-2009.* The data used in this analysis is self-reported secondary data without identifiers and is part of a publicly accessible secondary dataset.
Description of Action: Approved

Study #: 50169
Title of Study: Drug Use Health Profile
Principal Investigator: Bruce Taylor
Date Approved: August 13, 2014
Description of Study: The purpose of this study is to gather demographic, behavioral and service utilization data on Virginians who are injecting drug users, in order to more effectively provide HIV, Hepatitis, and STD prevention and care services to this population. Surveys will be administered through partnering organizations (methadone clinics, substance abuse treatment centers, etc) to Virginia residents who

have injected a non-prescribed drug in the past sixty days. Participants who are interested in participating in the study will be provided an information sheet and a consent form. To minimize a risk regarding a breach in confidentiality the subject's name will not be used to identify them on any study records. Signed consent forms will be stored separately. A workgroup established by VDH's Division of Disease Prevention will monitor data and serve as a data safety monitoring board. Participants will receive a $10 gift card.
Description of Action: Approved

Study #: 50170
Title of Study: Cost Analysis of Critical Congenital Heart Disease (CCHD)
Principal Investigator: Michelle Morris, MPH
Date Approved: August 13, 2014
Description of Study: This study is part of the evaluation of the Critical Congenital Health Disease (CCHD) Demonstration Project, which is sponsored by the Health Resources and Services Administration (HRSA). This cost analysis study will provide an objective estimate of the burden/impact of CCHD screening on public health and healthcare systems. The proposed cost analysis will involve two parts – a time and motion study and a cost survey. The time and motion study will involve observing/timing nurses when they perform CCHD screening at birth hospitals. The study will not interfere with patient care. The survey will be administered via Survey Gizmo to nurses or the hospital administrators who voluntarily agree to participate in the study. No identifying information will be collected. Findings will be shared with key stakeholders and the general public.
Description of Action: Approved

Study #: 50171
Title of Study: Medical Assessment of Referral of Newly Arriving Refugees
Principal Investigator: Kristina Johnson, MD
Date Approved: August 14, 2014
Description of Study: The purpose of this study is to describe the process of medical evaluation and referral of newly arriving refugees in Virginia for the purpose of identifying areas for improvement for state health departments as well as for the International Family Medicine Clinic at UVA. The 13 refugee Virginia resettlement service providers and the health departments in the counties that they serve will be contacted by phone and email. A 15 to 20 minute telephone survey will be conducted by the principal investigator following verbal consent. Any physicians or other health care providers who have an established relationship with these agencies may also be included in the study. Procedures to protect the confidentiality of data are in place.
Description of Action: Approved

Study #: 50172
Title of Study: Substance Use among Pregnant Women in the New River Valley Health District of Southwest Virginia during 2013
Principal Investigator: Annemarie Anglim
Date Approved: August 20, 2014

Description of Study: This is a retrospective study to identify the types of patients that have the highest rate of prenatal substance use so that community resources can be targeted to that demographic of patients. The study will also help to reinforce the need for education and substance abuse counseling during the prenatal visit so that providers can identify at-risk patients earlier in pregnancy and encourage continuity and regularity of care. Birth records will be reviewed to identify the source of prenatal care and the number of prenatal visits in order to compare those that reported substance use and those who did not. The analysis of the data will not include any identifying information. Data confidentiality will be maintained as required by the New River Valley Health District.
Description of Action: Approved

Study #: 50173
Title of Study: Traffic Safety Disparities in Appalachia
Principal Investigator: Motao Zhu, MD, PhD
Date Approved: August 27, 2014
Description of Study: The purpose of this study is to compare Appalachian counties and non-Appalachian counties within Appalachian states on traffic safety behaviors via an analysis of existing Behavior Risk Factor Surveillance System (BRFFS) data on seatbelt use and driving after drinking. No personal identifying information is included in the data. There are no identified risks.
Description of Action: Approved

Study #: 50174
Title of Study: New River Valley Health District NACCHO CDSMP Workshop Evaluation
Principal Investigator: Sophie Wenzel, MPH
Date Approved: September 8, 2014
Description of Study: The purpose of this evaluation is to help the New River Health Department design a program sustainability plan and adjust the Chronic Disease Self Management Program (CDSMP) workshops as necessary. The workshops are open to people suffering from one or more chronic health conditions such as diabetes, arthritis, depression and lung disease. The workshops are open to the public. The evaluation will be conducted by administering a CDSMP Outcome Evaluation Questionnaire on three separate occasions. The participants will be asked to complete the questionnaire prior to the workshop, six weeks following the workshop and six months following the workshop. Participation is voluntary and the study includes the completion of an informed consent form. Names of participants will be collected in order to ensure the ability for follow-up. All participants will be assigned a numerical code and the key stored separately from completed questionnaires. The final report will not contain any participant identifying information.
Description of Action: Approved

Study #: 50175
Title of Study: Community Assessment of Public Health Emergency Response (CASPER) in Thomas Jefferson Health District
Principal Investigator: Stuart Hutter, MS, MPH, CPH
Date Approved: September 9, 2014

Description of Study: This study will use an epidemiologic technique – The Community Assessment for Public Health Emergency Response (CASPER)- to collect household-level information to gather and assess baseline household preparedness data within the Greater Charlottesville community and to assist in planning for emergencies. The household sample will consist of 210 households chosen through a two-staged probability sampling technique. Trained research staff will conduct interviews with adult households using both paper/pen and electronically using Android tablets. Identifiable information will not be collected on the survey form. All household information from the surveys will be accessible to only the VDH CASPER team and protected in accordance with VDH policy. NOTE: If interviewed persons request information or assistance from the health department staff that cannot be immediately addressed, a referral form will be completed and turned in to the health department for appropriate response. These forms will be maintained according to the VDH Confidentiality Policy.
Description of Action: Approved

Study#: 50176
Title of Study: Risk Factors for Infection with Shiga-toxin Producing E-Coli (STEC) in Virginia: focus on Animal Exposure
Principal Investigator: Francois Elvinger, Ph.D., Patricia Baltasar, PhD candidate
Date Approved: October 21, 2014
Description of Study: Shiga toxin producing Escherichia coli (STEC) are bacteria that pose a significant threat to human and animal health. This study will focus on answering the following questions: which potential routes of infection are present, is there an association between clinical signs and potential routes of infection? Accounting for differences in population density, are cases mostly rural or urban residents and how does contact with animals (especially cattle) compare to other potential risk factors regarding infection with STEC. De-identified data from Virginia Electronic Disease Surveillance System will be analyzed. Addresses are geocoded only to latitude/longitude degree coordinates and will not allow for precision to distinguish between households. The researchers have signed VDH's assurance of confidentially. The researcher states that all data will be in a password protected computer. Study was approved by Virginia Tech IRB.
Description of Action: Approved

Study#: 50177
Title of Study: Community Health Survey using Community Assessment Emergency Response (CASPER) Methodology
Principal Investigator: Michelle Winz
Date Approved: October 30, 2014
Description of Study: To rapidly assess the health status and needs of a population for public health, particularly following a disaster. CASPER is an epidemiologic technique designed to collect household-level information about a specific community rapidly and cost-effectively. Gain experience in conducting type of community needs assessments for potential use following an actual emergency and to learn about the people living in the Portsmouth Health District, including their access to healthcare, physical activity and nutrition. CASPERs are frequently conducted following a disaster, but they can also be used to gather information in non-disaster settings. The

information obtained is compiled into a formal report, provides situational awareness and the timely, accurate, representative data are useful to decision makers when allocating resources, evaluating programs and planning response activities. The objectives are to exercise and train public health professionals, especially in emergency situations; gather and assess baseline household data; engage communities providing health education; develop training materials; meet grant requirements and learn to use ArcGIS and EPI-info 7 software. All interviewees will be 18 years or older and provide verbal consent prior to the interview. Paper forms containing identifiable information will also be maintained, stored and secured in accordance with VDH Confidentiality Policy. All participants in the pilot CASPER will be receiving training on the CASPER process and methodology, interviewing techniques, safety in the field being aware of the VDH Confidentiality Policy. The final report will be distributed to all stakeholders with all training materials to be used by other jurisdictions interested in performing this kind of assessment.

Description of Action: Approved

Study#: 50179
Title of Study: Cost Analysis of Critical Congenital Heart Disease (CCHD) Screening
Principal Investigator: Jennifer MacDonald, RN, BSN, MPH
Date Approved: December 10, 2014
Description of Study: The purpose of this study is to conduct a cost analysis of conducting the CCHD screening. Part of the evaluation of the CCHD Demonstration Project, which is sponsored by the Health Resources and Services Administration (HRSA), we are conducting an analysis of cost exclusive to CCHD screening per infant, including follow-up care for abnormal screens. The cost analysis will involve two parts- a time and motion study, a cost survey- which will be conducted at 8-10 birth hospitals in the Commonwealth of Virginia. An informational sheet explaining the study will be provided to all participants. If the birth hospital typically conducts CCHS screenings in a patient's room, the parent permission will be requested to observe the screening; cost survey will be electronically administered to nurses or hospital administrators who voluntarily agree to participate via internet. The information collected will provide an objective estimate of the burden/impact of CCHD screening on public health and healthcare systems. This study will fill the current literature gap on CCHD screening costs and address perceived barriers to implementation among other states and healthcare providers. The result will also be used to improve the efficiency of the screening process. No unique identifying information regarding the patient will be collected; final analysis, hospital information will be de-identified. Findings will be presented in aggregate when shared with key stakeholders and the general public.
Description of Action: Approved

II. ANY SIGNIFICANT DEVIATIONS FROM PROPOSALS AS APPROVED:

None

III. A LIST OF COMMITTEE MEMBERS, THEIR QUALIFICATIONS FOR SERVICE ON THE COMMITTEE, AND THEIR INSTITUTIONAL AFFILIATION: See attached.

IV. A COPY OF THE MINUTES OF ANY COMMITTEE MEETINGS CONDUCTED: See attached.

VDH IRB 2014		
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		
Jeffrey Stover	MPH, Public Health Epidemiology (resigned effective 1/6/2014)	Virginia Department of Health
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	Virginia Department of Health
Cecilia Barbosa	MPH (VCU Doctoral Candidate)	Community Representative
ALTERNATE MEMBERS		
Vacant		