

**REPORT TO THE COMMISSIONER:  
ACTIVITIES OF THE VDH IRB FOR  
CALENDAR YEAR 2010**

**Submitted by**

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Chair, VDH IRB**

## **REPORT TO THE COMMISSIONER: ACTIVITIES OF THE VDH IRB FOR CALENDAR YEAR 2010**

Regulations for the conduct of human research, developed and approved by the Board of Health, became effective on July 1, 1993. According to those regulations, prior to the initiation of a human research project by any institution or agency funded or licensed by the health department, a description of the proposed human research project shall be submitted to a research review committee for review and approval. 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, 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 "exemption 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, the IRB Chair or a designated voting member or group of voting members review the proposed research rather than the entire IRB.

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".

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 5-20-10) during calendar year 2010.

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

**A. Full Board Reviews**

None.

**B. Expedited Reviews:**

**Study #:** 40105  
**Title of Study:** Virginia Comprehensive Cancer Control Project  
**Principal Investigator:** Jean Gaare Eby, ScD, James Martindale, Ph.D. and Christina Sheffield  
**Date approved:** January 21, 2010  
**Description of Study:** This study will use state cancer registry data to compare cancer-related health indicators by demographic groups (age, race, sex and locality) and over time. The findings will be used to increase general awareness of cancer health disparities and to identify priority populations for cancer related resource allocations.

**Study #:** 40106  
**Title of Study:** Forteo Patient Registry  
**Principal Investigator:** Alicia Gilseman, Ph.D., GHBX Program Director  
**Date approved:** January 21, 2010  
**Description of Study:** This study will link data from tumor registries to determine if there is a higher incidence of osteosarcoma among adult patients who are being treated for osteoporosis with Forteo (a drug developed by Eli Lilly). This study is being conducted in cooperation with over 40 state, regional and center based cancer registries.

**Study #:** 40107  
**Title of Study:** Baby Basics Moms Club  
**Principal Investigator:** Merry McKenna  
**Date approved:** January 21, 2010  
**Description of Study:** This study is an evaluation of the Baby Basics Moms Club prenatal health literacy program that addresses health disparities in birth outcomes. Both process and outcome measures are incorporated in the evaluation, to include pre- and post test surveys, surveys of satisfaction and mechanisms for attendance and referral tracking.

**Study #:** 40108  
**Title of Study:** Enhanced Label to Promote Patient Understanding and Use  
**Principal Investigator:** Michael S. Wolf, Ph.D., MPH  
**Date approved:** February 18, 2010  
**Description of Study:** This study will test the efficacy of an evidence-based, enhanced prescription container label design as compared to the standard label format in an effort to improve the understanding of instructions for use for older diabetic patients.

**Study #:** 40109  
**Title of Study:** Prenatal Education Video Study

**Principal Investigator:** Ann L. Kellams, MD, IBCLC, FAAP  
**Date approved:** February 25, 2010  
**Description of Study:** This study will evaluate the efficacy of a video-based intervention intended to increase the initiation, duration and exclusivity of breastfeeding among WIC-eligible women.

**Study #:** 40110  
**Title of Study:** Improving the Management of Tuberculosis in Patients from Virginia Using the Whole-Blood Bactericidal Assay  
**Principal Investigator:** Scott K. Heysell, MD, MPH  
**Date approved:** April 19, 2010  
**Description of Study:** This study will compare a whole blood bactericidal assay for tuberculosis to serum drug levels as a predictor of failure of response to anti-tuberculosis medications and assess if a whole-blood bactericidal assay will identify a subset of patients in whom the correction of subtherapeutic drug levels will lead to improved response to anti-tuberculosis medications.

**Study #:** 40111  
**Title of Study:** The Use of Progesterone by Obstetrics Providers in Richmond Virginia  
**Principal Investigator:** Cheryl Bodamer, PhD, MPH  
**Date approved:** May 7, 2010  
**Description of Study:** This study will investigate OB/GYN clinician's practices in the Richmond metro area regarding the use of progesterone to prevent preterm labor through survey research. Findings will be used to inform future recommendations for promoting best practices.

**Study #:** 40112  
**Title of Study:** Evaluation of the Syphilis Reactor Grid  
**Principal Investigator:** Christine Flavin, MPH  
**Date approved:** May 29, 2010  
**Description of Study:** This study will evaluate the State's syphilis reactor grid within the Richmond metro area to assess its accuracy and reliability as a tool for prioritizing investigations.

**Study #:** 40113  
**Title of Study:** Oral Health Assessment of Virginia Adults at the Mission of Mercy (MOM) Projects  
**Principal Investigator:** Karen C. Day  
**Date approved:** July 7, 2010  
**Description of Study:** This study will assess the oral and general health needs of recipients of dental services at the Wise and Grundy Mission of Mercy projects. Findings will be used for policy and program planning purposes.

**Study #:** 40114  
**Title of Study:** Virginia Youth Risk Behavior Survey (The Virginia Youth Survey Project)  
**Principal Investigator:** Janice M. Hicks, PhD

**Date approved:** July 30, 2010  
**Description of Study:** This study will assess trends in priority health-risk behaviors among Virginia public school students in grades 9 – 12. Findings will be used to evaluate the impact of broad school and community interventions.

**Study #:** 40115  
**Title of Study:** Exploring Risk and Perception of Risk in the Diagnosis of Breast Cancer in Smyth County, Virginia

**Principal Investigator:** Laura Jensen  
**Date approved:** August 12, 2010  
**Description of Study:** This study will explore the community perceptions of breast cancer in Smyth County, Virginia in order to gain a better understanding of whether, how and why breast cancer appears to be under-diagnosed and/or under-reported in this county.

**Study #:** 40116  
**Title of Study:** Health Effects: Air Pollution and Adverse Birth Outcomes in the US

**Principal Investigator:** Naresh Kumar  
**Date approved:** August 17, 2010  
**Description of Study:** This study will use modern advances in satellite remote sensing coupled with chemical dispersion models and geostatistical methods to compute location- and source-specific daily concentrations of airborne particulates of different sizes for the entire continental US from 2000 – 2010. These estimates will be used to compute air pollution exposure and to model health effects of air pollution exposure, with a focus on birth outcomes.

**Study #:** 40117  
**Title of Study:** Community Outreach and Volunteer Training: Medical Reserve Corps Study

**Principal Investigator:** Jack Harrald  
**Date approved:** August 30, 2010  
**Description of Study:** This study will examine the potential use of social networks such as neighborhood associations, community centers and religious organizations; in coordination with existing outreach efforts by groups including the Medical Reserve Corps to facilitate lasting community-based emergency preparedness and response.

**Study #:** 40118  
**Title of Study:** Cancer Risk Among Firefighters and Emergency Service Rescuers and Officers Exposed to the World Trade Center Disaster

**Principal Investigator:** David J. Prezant, MD  
**Date approved:** August 12, 2010  
**Description of Study:** This study will look at the incidence and prevalence of cancer for firefighters and other emergency responders who were exposed to the World Trade Center collapse on September 11, 2001.

**Study #:** 40119  
**Title of Study:** Understanding Oral Health and Health Care in Lenowisco and Cumberland Plateau Health Districts  
**Principal Investigator:** Sarah Raskin  
**Date approved:** September 16, 2010  
**Description of Study:** This study will describe and analyze various aspects of oral health and healthcare in southwest Virginia, with a focus on those participating in the pilot project in southwest Virginia allowing dental hygienists to provide basic dental services.

**Study #:** 40120  
**Title of Study:** Endometrial Cancer in Virginia  
**Principal Investigator:** Madeleine Courtney-Brooks, MD  
**Date approved:** September 21, 2010  
**Description of Study:** This study will look at women diagnosed with endometrial cancer to better understand patterns of care in relationship to location of residence, place of diagnosis, place of treatment and overall mortality. The study will also look at whether trends in obesity and tobacco use may have had an impact on the diagnosis of uterine cancer.

**Study #:** 40121  
**Title of Study:** An Art-Based Psychoeducational Group for Pregnant Teenagers  
**Principal Investigator:** Laura S. Maloney, ATR-BC, LPC, LMFT  
**Date approved:** October 4, 2010  
**Description of Study:** This study will evaluate the efficacy of a 5 week art-based psychoeducational group with pregnant teens designed to increase their preparedness for pregnancy and motherhood.

**Study #:** 40122  
**Title of Study:** Evaluation of Academic Performance of Hampton Healthy Start Graduates  
**Principal Investigator:** Jerrica Nichols, MPH Student  
**Date approved:** October 4, 2010  
**Description of Study:** This study will evaluate the impact of the Hampton Healthy Start program on the academic performance of program graduates.

**Study #:** 40123  
**Title of Study:** Evaluation of Host Immune Responses to Hepatitis B Vaccine Among Patients Vaccinated in Response to Hepatitis B Outbreak Investigation  
**Principal Investigator:** Thomas John Bender, MD, PhD  
**Date approved:** November 4, 2010  
**Description of Study:** This study will identify the proportion of hepatitis B vaccine recipients who acquired vaccine-induced immunity among a group of adults identified as susceptible to hepatitis B virus infection during an outbreak at an assisted living facility and evaluate immune and other host factors related to poor or non-response.

**Study #:** 40124  
**Title of Study:** Latinas' Contraception Experience and Planning (LCEP)  
**Principal Investigator:** Jacqueline M. McGrath  
**Date approved:** November 3, 2010  
**Description of Study:** This study will obtain information from Latinas during their three months postpartum period about their current perceptions about contraception, their experience with contraception, and their contraception planning process. Findings will be used to design interventions intended to improve the use of contraception among Latinas, who are the only ethnic group with an increase in rates of unintended pregnancy.

**Study #:** 40125  
**Title of Study:** The Vaginal Microbiome: Disease, Genetics and the Environment  
**Principal Investigator:** Gregory Buck  
**Date approved:** December 3, 2010  
**Description of Study:** This study will examine: 1) a woman's genetic composition to see if it significantly affects the ability of certain commensal, parasitic and pathogenic microbes to colonize and/or infect the genital tract; 2) examine whether altered physiologic and pathologic conditions or environmental exposures alter the vaginal microenvironment and 3) whether infectious diseases predictably alter the vaginal microbiome and lead to an impact on the disease process and/or create a greater susceptibility to other infectious diseases.,

### C. Exemption Reviews

**Study #:** 50072  
**Title of Study:** Surveillance for the Virginia Asthma Control Program  
**Principal Investigator:** Henry J. Carretta, Ph.D., MPH  
**Date approved:** January 6, 2010  
**Description of Study:** This is a retrospective longitudinal analysis of data (1999-2008) to look at population level indicators of the burden of disease in the Virginia population with asthma for the Virginia Asthma Control Project (VACP). Selected indicators will include prevalence, inpatient hospitalizations, mortality and their associated behavioral risk factors.

**Study #:** 50073  
**Title of Study:** Therapeutic drug monitoring among patients slow to respond to treatment for tuberculosis  
**Principal Investigator:** Scott K. Heysell, M.D., MPH  
**Date approved:** January 4, 2010  
**Description of Study:** This study will look at the population of adults initially treated for drug-susceptible pulmonary tuberculosis in Virginia between January 2008 – May 2009. The study will describe the extent to which slow-responders to TB treatment are related to subtherapeutic drug levels and seek to identify patients at risk of having subtherapeutic drug levels.

**Study #:** 50074  
**Title of Study:** Behavioral Risk Factor Surveillance System (BRFSS) – State Added Questions  
**Principal Investigator:** Susan Kennedy Spain  
**Date approved:** January 10, 2010  
**Description of Study:** This study will assess the health status and risk behaviors of Virginia residents pertaining to disabilities, folic acid use, tobacco use and skin cancer and sun exposure.

**Study #:** 50075  
**Title of Study:** Comparison of Severe H1N1 Cases with Severe Seasonal Influenza Cases  
**Principal Investigator:** Timothy Powell  
**Date approved:** January 25, 2010  
**Description of Study:** This study will compare the populations hospitalized for the 2009 H1N1 strain of influenza with those from the 2009-09 seasonal strain to compare and contrast the morbidity between these two strains of the virus.

**Study #:** 50076  
**Title of Study:** The Evaluation of the Content and Quality of Prenatal Care in Virginia Using PRAMS  
**Principal Investigator:** Susan Cha  
**Date approved:** February 25, 2010  
**Description of Study:** This study will use 2007-2008 Pregnancy Risk Assessment and Monitoring System (PRAMS) data to determine the association between various components of prenatal healthcare received during pregnancy and pre-term live births. Specifically, it will look at the association Kotelchuck's Adequacy of Prenatal Care Utilization (APNCA) index with preterm live births in Virginia, compare components of prenatal care received during pregnancy across various levels of the APNCU index, and assess the association of adequacy of prenatal care with maternal post-pregnancy health behaviors.

**Study #:** 50077  
**Title of Study:** Mercury Exposure of Pregnant Women Along the South River and South Fork Shenandoah River  
**Principal Investigator:** Jonathan Falk, MPH  
**Date approved:** April 1, 2010  
**Description of Study:** This study will examine the hypothesis that certain risk factors, such as household size and race/ethnicity, may be associated with increased consumption of fish from the South River and South Fork Shenandoah River. These rivers have had fish consumption advisories in place since the 1970s due to the potentially harmful levels of mercury released into the river between 1929 – 1950. Increased consumption of fish from these rivers result in increased exposure to mercury in pregnant women.



**Study #:** 50078  
**Title of Study:** Geospatial Analysis of Breast Cancer Incidence in Virginia 2000-2005: A Methodological, Analytical and Policy Perspective  
**Principal Investigator:** Kenneth Studer, Ph.D.  
**Date approved:** March 23, 2010  
**Description of Study:** This study will look at the spatial distribution of Virginia's breast cancer incidences as found in the Virginia Cancer Registry database for 2000 – 2005. The study will specifically look at the incidence of under-reporting throughout the state, and determine if data collection methodologies could be influencing breast cancer cluster formation and detection.

**Study #:** 50079  
**Title of Study:** Pharmacogenomic Analysis of Methadone and Mixed Drug Deaths – Virginia 2007 - 2010  
**Principal Investigator:** Jeff Jentzen, MD, PhD  
**Date approved:** April 1, 2010  
**Description of Study:** This study will attempt to explore the root cause for the increase in drug deaths over the past decade in Virginia. Specifically being examined is whether the increase is due to increased consumption and distribution or from a particular distribution of genotypic variants that decreased drug metabolism in certain individuals resulting in subsequent death.

**Study #:** 50080  
**Title of Study:** Influenza-like Illness Survey at Washington and Lee University During an H1N1 Outbreak in May 2009  
**Principal Investigator:** Jun Yang  
**Date approved:** N/A  
**Description of Study:** This study was submitted to the VDH IRB for review, but because it is not within the allowed scope of an IRB to retroactively review research and because this “study” also fit the criteria for public health surveillance, the VDH did not find it necessary to review this protocol.

**Study #:** 50081  
**Title of Study:** Focus Group Evaluation of Childhood Injury Prevention Program Efforts  
**Principal Investigator:** Stephanie Goodman, MPH  
**Date approved:** June 5, 2010  
**Description of Study:** This study looks at child injury prevention programs and efforts among harder-to-reach populations. Focus groups will be used to assess parent/caregiver attitudes, beliefs and practices regarding recommended child safety best practices like child car seats, safe sleep and bike helmets.

**Study #:** 50082  
**Title of Study:** EHDI Midwifery Evaluation  
**Principal Investigator:** Ashleigh Howard  
**Date approved:** June 24, 2010

**Description of Study:** This study of midwives will assess the needs of infants born at home and in birthing centers in order to help the Virginia Early Hearing Detection and Intervention Program better plan for and provide support to midwives and parents regarding newborn hearing screenings.

**Study #:** 50083  
**Title of Study:** Data Analysis for the 2011 Health Equity Report  
**Principal Investigator:** Jeff Alwang  
**Date approved:** July 9, 2010  
**Description of Study:** This study will include analyses of published literature, analyses of data from the U.S. Census, Virginia Health Information data, and mortality data to look at disparities in health outcomes in relationship to social and demographic characteristics. Additionally, analyses will be conducted to develop economic cost estimates associated with these disparities.

**Study #:** 50084  
**Title of Study:** Influenza Incidence Surveillance Project  
**Principal Investigator:** Lesliann Helmus  
**Date approved:** July 6, 2010  
**Description of Study:** This study will evaluate the Influenza Incidence Surveillance Project, confirming influenza infection in individuals seeking medical attention with acute respiratory illness and evaluating circulating strains and vaccination history to better characterize disease activity during the influenza season in Virginia.

**Study #:** 50085  
**Title of Study:** The Impact of Comorbid Birth Defects on the Prevalence and Timing of Screening, Diagnosis and Treatment of Congenital Hearing Loss.  
**Principal Investigator:** Derek A. Chapman, Ph.D.  
**Date approved:** July 12, 2010  
**Description of Study:** This study will use examine data from the statewide birth defects and hearing screening registry to determine the prevalence of congenital hearing loss within specific categories of birth defects, determine the prevalence of specific categories of comorbid birth defects among infants with congenital hearing loss and quantify the impact of comorbid birth defects on the timing of screening, diagnosis and treatment of infants with congenital hearing loss.

**Study #:** 50086  
**Title of Study:** Safe in the City: The Impact of a Sexually Transmitted Disease Prevention Video on Prevention Knowledge and Planned Sexual Behavior in African Americans.  
**Principal Investigator:** Shirley Power Smith, PhD and Margaret Teu, RN MS WHNP-BC  
**Date approved:** August 8, 2010  
**Description of Study:** This study will assess the impact of viewing an STD intervention/prevention video on the STD prevention knowledge and future behavioral intentions among young African American adults who access services through the Richmond City Health Department STD clinic.

**Study #:** 50087  
**Title of Study:** BRFSS Analysis for Virginia Health Promotion for People with Disabilities Project  
**Principal Investigator:** Donna Gilles, EdD  
**Date approved:** August 16, 2011  
**Description of Study:** This study will analyze the Virginia Behavioral Risk Factor Surveillance Survey (BRFSS) data to look at trends and offer descriptive analyses pertaining to the Health Status of Virginians with Disabilities for the years 2007 – 2009.

**Study #:** 50088  
**Title of Study:** Grandparent-Headed Families and Virginia WIC: An Examination of Service Awareness, Utilization and Delivery  
**Principal Investigator:** Megan L. Dolbin-MacNab, Ph.D., LMFT  
**Date approved:** August 12, 2010  
**Description of Study:** This study will assess the nutritional needs of young children and their custodial grandparents, identify the government assistance programs that custodial grandparents use to meet those needs, describe barriers to service awareness and utilization for government assistance programs and explicate WIC policies and procedures that influence custodial grandparents from accessing services. Results of the study will be used to create educational outreach materials and identify best practices for WIC personnel to use when identifying, reaching and serving young children who are raised by grandparents.

**Study #:** 50089  
**Title of Study:** Best Practices and Analysis of Gaps and Barriers to Widespread Adoption  
**Principal Investigator:** Jane L. McDaniel, Ph.D.  
**Date approved:** September 15, 2010  
**Description of Study:** This study will use key informant interviews and surveys to identify best practices, training gaps, and barriers to the adoption of programs for training psychology students to provide mental health services to rural residents. A compendium of training programs and best practices will be developed as a result of study findings.

**Study #:** 50090  
**Title of Study:** Underreporting of *Vibrio vulnificus* Infections in the Chesapeake Bay Area  
**Principal Investigator:** Peter S. J. Lees, PhD  
**Date approved:** December 15, 2010  
**Description of Study:** This study will investigate the potential underreported burden of *Vibrio vulnificus* infection in the Chesapeake Bay area. The study will first investigate previously reported cases in Virginia and Maryland in order to have a better understanding of the characteristics of the cases. Afterwards, a small survey of area health facilities or laboratories will be used to identify the magnitude of underreporting in the Chesapeake Bay region.

**II. ANY SIGNIFICANT DEVIATIONS FROM PROPOSALS AS APPROVED:**

**Study #:** 40095  
**Title of Study:** National Study of Determinants of Early Diagnosis, Prevention and Treatment of TB  
**Principal Investigator:** Suzanne Keller, M.A.  
**Description:** During a period between August 30, 2010 and September 7, 2010 an interviewer lost a completed questionnaire booklet, signed consent document and medical record abstraction form for a participant who was interviewed. The documents included identifying information about the participant including full name, address, telephone number and TB state case number. The interviewer was traveling to counties in southwest Virginia over that period of time, abstracting records from three different local health departments. This included two overnight stays at a hotel. The lost documents were not discovered until the interviewer returned to the office. A corrective action plan has been developed to help ensure security of documents and to protect the confidentiality of subjects while in transport. This includes the use of a locked portable storage container that is labeled with the interviewers contact information should it become lost and no other identifiers and the placement of the locked container in a locked car trunk while in transport. During overnight trips, the locked container should accompany the interviewer into the hotel room and not be left in the vehicle.

**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.

<b>VDH IRB 2010</b>		
<b>Committee Members</b>	<b>Qualifications for Service</b>	<b>Institutional Affiliation</b>
<b>IRB CHAIR</b>		
Kathy H. Wibberly	Ph.D. in Counseling Psychology and Director, Division of Primary Care and Rural Health in Office of Minority Health and Health Equity	Virginia Department of Health
<b>VOTING MEMBERS</b>		
J. Elisha Burke	D.Min. and Director, Men's and Health and Wellness Ministry	Baptist General Convention of Virginia
Ana Lizzette Colon	M.P.H. in Epidemiology & Regional Surveillance Coordinator	Virginia Department of Health, Eastern Region Field Office
Bethany J. Geldmaker	Ph.D. in Nursing & Child Health Care Consultant	Virginia Department of Health
Gail J. Jennings	Ph.D. in Psychology & Program Director, Virginia Breast and Cervical Cancer Early Detection Program	Virginia Department of Health
Gregory B. Stolcis (member resigned April 6, 2010)	Ph.D. in Public Policy & Administration and Director, Acute Care Division, Center for Quality Health Care Services and Consumer Protection	Virginia Department of Health
David H. Trump	M.D., M.P.H., FACPM and Director, Peninsula Health District	Peninsula Health District
<b>ALTERNATE MEMBERS</b>		
Vacant		