

**REPORT TO THE COMMISSIONER:**

**ACTIVITIES OF THE VIRGINIA  
DEPARTMENT OF HEALTH INSTITUTIONAL  
REVIEW BOARD FOR CALENDAR YEAR  
2009**

**Submitted by**

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Chair, VDH IRB**

## **REPORT TO THE COMMISSIONER: ACTIVITIES OF THE VDH IRB FOR CALENDAR YEAR 2009**

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 and updated in March 2005.

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 activity are considered research but may be declared exempt from review by the IRB. This determination must be made by the IRB prior to the research being conducted. If a study falls into one of the exempt categories, researchers still have ethical responsibilities to protect participants' rights.

For certain kinds of research involving no more than minimal risk, and for minor changes in approved research, the IRB Chair or a designated voting member or group of voting members review the proposed research rather than the entire IRB. This type of review is called "expedited review".

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 of the VDH IRB as per State regulations for the conduct of human research (12 VAC 5-20-10) during calendar year 2009.

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

**A. Full Board Reviews**

None.

**B. Expedited Reviews:**

**Study #:** 40098  
**Title of Study:** Invasive MRSA in South Hampton Roads Virginia  
**Principal Investigator:** Batrina Martin, Ph.D. Candidate  
**Date approved:** January 5, 2009  
**Description of Study:** This study uses cross-sectional survey research design to investigate whether there is a significant relationship between the incidence and prevalence of invasive MRSA and management competence in implementing health care general systems theory such as ORYX quality measures in South Hampton Roads Virginia during the first 6 months of 2008.

**Study #:** 40099  
**Title of Study:** Evaluation of Vestibular Deficits and Interventions in Hearing Impaired Infants  
**Principal Investigator:** Kelley Dodson, M.D.  
**Date approved:** April 23, 2009  
**Description of Study:** This study looks at hearing impaired children ages 6 months to 4 years to see if children born with hearing impairment also have vestibular deficits. It was hypothesized that this may be the case because these sensory receptors are located in the same area of the inner ear. The study also looked at the hypothesis that congenitally deaf children with vestibular deficits might also have delayed motor development, weak soleus muscles and underdeveloped eye movements.

**Study #:** 40100  
**Title of Study:** An Evaluation of Adolescent Health Care and Services at the Thomas Jefferson Health District's Sexually Transmitted Disease Clinic in 2008  
**Principal Investigator:** Dr. Cirle Warren  
**Date approved:** July 2, 2009  
**Description of Study:** This retrospective chart review study looked at adolescent patients between the ages of 12 – 18 who visited the Thomas Jefferson Health District STD clinic during the 2008 calendar year. The study looked at utilization of clinic resources, patient characteristics, and follow-up compliance.

**Study #:** 40101  
**Title of Study:** Cancer Epidemiology in Adventists – A Low Risk Group  
**Principal Investigator:** Gary E. Fraser  
**Date approved:** August 7, 2009  
**Description of Study:** This cohort study explores associations between diet and other personal habits such as exercise and hormone use with cancer risk, particularly

cancers of the breast, colon and prostate. The study population includes Seventh-day Adventist Church members age 30 and above.

**Study #:** 40102  
**Title of Study:** Analysis of Urethral Exudates in Acute Gonorrhea  
**Principal Investigator:** Alison Criss, Ph.D.  
**Date approved:** August 14, 2009  
**Description of Study:** This is a study of the urethral secretions of men with gonorrhea who attended the Thomas Jefferson Health District STD clinic. The study is being conducted to test three hypotheses: 1) that strains of *N. gonorrhoeae* circulating in the population in Charlottesville, VA have difference susceptibilities to killing by human neutrophils; 2) that neutrophils from urethral secretions of men with gonorrhea can engulf *N. Gonorrhoeae* and some of the bacteria in these neutrophils are alive and dividing and 3) that urethral secretions from men with acute gonorrhea contain chemokines and cytokines that are pro-inflammatory, in keeping with the inflammatory nature of gonorrheal urethritis.

**Study #:** 40103  
**Title of Study:** Hampshires at Greenbrier Chinese Drywall Assessment  
**Principal Investigator:** Nancy M. Welch, MD, MHA, MBA  
**Date approved:** August 25, 2009  
**Description of Study:** This study evaluates residents of the Hampshires subdivision in Chesapeake pertaining to the presence or absence of symptoms associated with residing in a house that either was or was not constructed using Chinese drywall and/or post remediation of the home.

**Study #:** 40104  
**Title of Study:** Health Equity Education, Awareness, and Advocacy through Utilizing “Unnatural Causes: Is Inequality Making Us Sick?”  
**Principal Investigator:** Anika T. Richards, MPH  
**Date approved:** August 31, 2009  
**Description of Study:** This study evaluates the impact of viewing the documentary film “Unnatural Causes: Is Health Inequality Making Us Sick” on a selected cohort of 100 individuals. The study will evaluate participants’ level of awareness, knowledge and advocacy surrounding issues related to health care inequality.

### C. Exemption Reviews

**Study #:** 50062  
**Title of Study:** Pregnancy Outcome Project (POP)  
**Principal Investigator:** Barbara H. Yager, RD, MEd  
**Date approved:** January 5, 2009  
**Description of Study:** This study reviews the medical records of pregnant women seen in WIC clinics in Charlottesville and Albemarle County during January 2006 – October 2008 to assess whether certain demographic, health and clinical indicators predict low birthweight and other adverse birth outcomes.

**Study #:** 50063  
**Title of Study:** Infection Control Practices in Animal Healthcare  
**Principal Investigator:** Catherine McManus, VMD, MPH, DACVPM  
**Date approved:** February 2, 2009  
**Description of Study:** This study assesses the types of infection control measures that are being practiced by animal healthcare providers within the Commonwealth through an online survey.

**Study #:** 50064  
**Title of Study:** Thomas Jefferson Health District BRFSS Study  
**Principal Investigator:** Peggy Brown Paviour, M.S., CHES  
**Date approved:** March 19, 2009  
**Description of Study:** This study compares key health indicators within the Thomas Jefferson Health District with that reported on the Behavioral Risk Factor Surveillance Survey (BRFSS) at the state level.

**Study #:** 50065  
**Title of Study:** Oral Health Education for Parents of Children with Special Health Care Needs  
**Principal Investigator:** Karen C. Day  
**Date approved:** May 4, 2009  
**Description of Study:** This study will assess the oral health knowledge and needs of parents and other caretakers of Children with Special Health Care Needs through the use of a survey (combination of email, mail and interviews).

**Study #:** 50066  
**Title of Study:** Risk Communication Awareness Evaluation of the Virginia Public Beaches Recreational Water Monitoring and Advisory Program  
**Principal Investigator:** Daniel Dietrich, M.S.  
**Date approved:** July 2, 2009  
**Description of Study:** This study assesses the efficacy of the swimming advisory/risk communication program found at public beach areas as a result of the beach water monitoring program that has been in existence in Virginia since 2003 using a survey design.

**Study #:** 50067  
**Title of Study:** Mortality and Air Pollution in the U.S. Metropolitan Statistical Areas, 2000 – 2008.  
**Principal Investigator:** Naresh Kumar  
**Date approved:** July 7, 2009  
**Description of Study:** This study looks at mortality and air pollution in the ten largest U.S. cities using spatial temporal resolutions, examining the impact of air quality estimated from satellite remote sensing at the smallest possible geographic unit for which mortality data will be available and evaluating the feasibility of satellite remote sensing to compute exposure to ambient airborne particles of different sizes.

**Study #:** 50068  
**Title of Study:** Southwest Virginia Community Health Needs Assessment: RAM Clinic – Wise County, 2009  
**Principal Investigator:** Susan L. Triggs, RN, MPH  
**Date approved:** July 22, 2009  
**Description of Study:** This study assesses the overall community health needs of area residents who attended the Remote Area Medical (RAM) clinic in July 2009, with the goal of better understanding the quality and availability of public service programs in southwest Virginia. A survey design is used.

**Study #:** 50069  
**Title of Study:** Recurrence Rate and Factors Associated with Late Preterm Deliveries  
**Principal Investigator:** Derek Chapman, Ph.D.  
**Date approved:** August 3, 2009  
**Description of Study:** This study uses vital records data to assess whether or not having a late preterm delivery with a first birth increases risk of having a preterm or later preterm delivery in a second pregnancy.

**Study #:** 50070  
**Title of Study:** Small Area Estimation of Risk Factors: Baseline and Two-Year Projections for U.S. Counties  
**Principal Investigator:** Ali Mokdad  
**Date approved:** October 22, 2009  
**Description of Study:** This study tests out a new approach for making small area estimates of risk factor prevalence rates for counties and cities in the U.S. to see if it would be possible to obtain more accurate and robust rates of the following Behavioral Risk Factor Surveillance Survey (BRFSS) risk factors: obesity, tobacco use, high blood pressure awareness, high cholesterol awareness, physical activity and diabetes.

**Study #:** 50071  
**Title of Study:** Teen Pregnancy Prevention Initiative Evaluation Pre and Post Survey  
**Principal Investigator:** Joanne Boise  
**Date approved:** October 23, 2009  
**Description of Study:** This study evaluates the effectiveness of the community based programs funded through the Teen Pregnancy Prevention Initiative using a pre-post- intervention survey comprised of a subset of questions from the Youth Risk Behavior Survey.

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

**Study #:** 40092  
**Title of Study:** Flight Attendants Health Study: The Incidence of Breast and Other Cancers Among Female Flight Attendants  
**Principal Investigator:** Lynne Pinkerton  
**Type of Review:** Incident Report

**Description:**

Data with individual identifiers that was password protected and encrypted was misplaced by a VDH employee who has since left VDH. Although it was very fortunate that precautions were in place to ensure that password protection and encryption were in place, the VDH IRB still recommended to the office director that there be some protocols for tracking data and data requests, as well as procedures for collecting data and data storage devices from employees when they leave a position. There was the potential, in this situation, for an employee who is no longer with VDH to have possession of both the data and the password. This is a potential threat to the security of this data and could have created a breach of confidentiality. It was also recommended that data sets that are received by VDH for research purposes (including the linkage of data sets) be backed up on the VDH server to prevent its loss, and that portable storage devices with such data not be removed from VDH premises. Finally, it was recommended that the agency explore using secure ftp for the transfer of data sets for research purposes.

**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 2009</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 Public Health Policy	Virginia Department of Health
<b>VOTING MEMBERS</b>		
J. Elisha Burke (appointment began August 2009)	D.Min. and Director, Men's Ministry 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	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		