

**REPORT TO THE COMMISSIONER:
ACTIVITIES OF THE VDH IRB FOR
CALENDAR YEAR 2007**

Submitted by

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Chair, VDH IRB**

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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. The Virginia Department of Health (VDH) had been relying on the research review committees of academic institutions around the state; however, this precluded VDH's ability to conduct research that did not have a co-investigator at an academic institution. A committee was formed in the spring of 2000 to explore the viability of developing a research review committee (Institutional Review Board) at VDH and a determination was made to proceed. Committee members were appointed and a policy document, *The Institutional Review Board (IRB) of the Virginia Department of Health: 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' effort to establish effective communication with IRBs. In addition, receiving an assurance from OHRP formalizes an institution's commitment to protect human subjects.

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 2007.

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

A. Full Board Reviews

None.

B. Expedited Reviews:

Study #: 40073
Principal Investigator: Holly Tiller, CHES
Title of Protocol: "Petersburg ARC Physical Activity and Nutrition Program"
Date approved: This study was reviewed and issues were identified with the reading level of the consent form. The PI was asked to revise and resubmit. The revised consent form, although at a slightly lower reading level, was still at approximately an 8th grade level. Given the diminished capacity of the target audience, the PI was asked to address who would be signing the consent form – whether it would be a guardian or the participant him/herself. The PI subsequently decided to withdraw the study from review.

Description of Study: This study was, as proposed, a two-year pilot project to evaluate the effectiveness of a once per week moderate stretching and physical activity session provided to the ARC of Petersburg consumers. Health improvements, to include measures of weight and blood pressure, would be tracked. In the 2nd year of the study, the VDH Diabetes Prevention and Control Project would also provide a healthy eating instructional session.

Study #: 40075
Principal Investigator: Lynne Penberthy, M.D., MPH
Title of Protocol: “Improving Capture of Chemotherapy Information Using Physician Office Billing”
Date approved: February 2, 2007
Description of Study: This study will assess the feasibility of implementing electronic capture of missing cancer surveillance data on chemotherapy treatment from the claims billing stream in community oncology practices to the Virginia Cancer Registry.

Study #: 40076
Title of Study: Black Women's Health Study: A Follow-Up Study
Principal Investigator: Lynn Rosenberg, Sc.D.
Date approved: March 7, 2007
Description of Study: This study evaluates the influence of important risk factors on the occurrence of diseases that have a major impact on the health of black women. The aims of the study include prospective analyses of the influence of body size, physical activity, diet, alcohol consumption, oral-contraceptive use, hair relaxer use, cigarette smoking, and psychosocial factors on the incidence of breast cancer in black women. Also being assessed are risk factors for rare cancers (as numbers become adequate) and the influence of genetic polymorphisms on susceptibility to cancer.

Study #: 40077
Title of Study: Matching of Mid-Atlantic Twin Registry (MATR) and Virginia Cancer Registry (VCR)
Principal Investigator: Lynn Rosenberg, Sc.D.
Date approved: March 5, 2007
Description of Study: The purpose of this study is to match MATR and VCR registrants in an effort to estimate the heritability of certain types of cancer in Virginia residents. Specifically the study will look at the feasibility of merging data from these registries, estimate the proportions of variance in cancer prevalence explained by genetic factors, shared environment and unique environment, and compare estimates of heritability among MATR twins with those identified in other twin registries.

Study #: 40078
Title of Study: Women's Health Study
Principal Investigator: Melissa Sutherland, M.S., FNP
Date approved: This study was reviewed and issues were identified pertaining to missing study materials. The study was later withdrawn by the P.I. as the P.I. was able to obtain the necessary sample size without using VDH patients/clients.

Description of Study: This study, as proposed, looks at the hypothesis that history of past sexual and/or partner abuse is correlated with engaging less frequently in “risk-reducing behaviors”, such as condom use. Experiencing cognitive dissociation (e.g., memory loss) is hypothesized to be a mediator between past abuse and not practicing safer sex.

Study #: 40079
Title of Study: 2007 Piedmont Health District Pilot Study
Principal Investigator: Karen C. Day
Date approved: March 28, 2007
Description of Study: This study will assess the effectiveness of the Basic Screening Survey in collecting reliable oral health information. This screening method is less invasive and time-intensive than other methods.

Study #: 40080
Title of Study: Hampton Roads VDH/VIMS Clam Project
Principal Investigator: Howard Kator, Ph.D.
Date approved: April 23, 2007
Description of Study: This study will assess the use of polymerase chain reaction (PCR) techniques to test for the presence of pathogenic viruses in shellfish and to optimize the use of such techniques for use on clam tissue. The PI will acquire norovirus from human stool during the development of the analytical technique to use as a laboratory standard.

Study #: 40081
Title of Study: Cancer Prevalence in Obese Women Who Underwent Bariatric Surgery
Principal Investigator: Susan Modesitt, MD
Date approved: July 9, 2007
Description of Study: This retrospective study will evaluate the prevalence and types of cancer in an obese population that underwent bariatric surgery. The P.I. hypothesizes that women undergoing bariatric surgery may have an increased prevalence of obesity related cancers compared to the general population. Data from the Virginia Cancer Registry will be among the data sets used to identify the subgroup of patients who have been diagnosed with cancer.

Study #: 40082
Title of Study: Online Training for a New Parent-Child Assessment Tool
Principal Investigator: Marilee Comfort, Ph.D., MPH
Date approved: July 30, 2007
Description of Study: This is an exploratory construct validation study of the Keys to Interactive Parenting Scale (KIPS). KIPS is a structure observation tool for parent-child interaction. Online training will be used to train family support workers in the use of the tool.

Study #: 40083
Title of Study: Flu Clues: A Childhood Influenza Vaccination Project
Principal Investigator: John Dreyzehner, MD, MPH, FACOEM

Date approved: August 20, 2007
Description of Study: This study will look at the effectiveness of providing the influenza vaccination to children between three and nine years of age in collaboration with the local Head Start programs and elementary schools on decreasing the impact of seasonal influenza in the community.

Study #: 40084
Title of Study: Integration of HIV/AIDS Testing and Prevention Services in the Three Local Title X Family Planning Projects
Principal Investigator: Deborah M. Harris
Date approved: October 19, 2007
Description of Study: This study will assess the effectiveness of implementation of the Rapid HIV oral antibody test as part of the standard of care for individuals seeking pregnancy screening or family planning services at health department Family Planning Clinics.

C. Exemption Reviews

Study #: 50043
Title of Protocol: Patient Utilization and Prehospital Treatment Characteristics of Virginia Emergency Medical Services
Principal Investigator: Sabina A. Braithwaite, MD, FACEP
Date approved: April 13, 2007
Description of Study: This study seeks to determine if there is a difference between overall on-scene times during potential life threatening conditions between rural and urban EMS systems and if providing ALS procedures contribute to any of the differences that may exist.

Study #: 50044
Title of Protocol: Obtaining Adult's Opinions About Teen Abstinence Programs In Virginia
Principal Investigator: Allen Lewis, Ph.D.
Date approved: May 8, 2007
Description of Study: This study will assess the attitudes and opinions of parents and other adults within a community regarding teen abstinence programs and activities.

Study #: 50045
Principal Investigator: Carrie Dolan
Title of Protocol: Health Disparities and Planning in Virginia: Poverty, HIV/AIDS and Sexually Transmitted Diseases (STDs)
Date approved: May 3, 2007
Description of Study: This study will look at STD/HIV/AIDS incidence rates and compare proportional differences found in target populations in Virginia by poverty levels at the census tract level. It is hypothesized that residents of poorer neighborhoods with disproportionately high STD rates are more susceptible to the transmission and acquisition of HIV/AIDS.

Study #: 50046

Title of Protocol: Refinement of an Instrument Measuring Public Health Nursing Competencies
Principal Investigator: Dawn Reckinger
Date approved: June 4, 2007
Description of Study: This study will assess the reliability of a public health nursing competency tool. The study will also be used to refine and further validate the instrument.

Study #: 50047
Title of Protocol: Disparities in Access to Mammography Screening in the Rural South
Principal Investigator: Linda Elting, Dr. Ph.H.
Date approved: July 13, 2007
Description of Study: This study examines health disparities in mammography screening in rural areas of the South. It is hypothesized that rural counties that lack access to mammography services, have populations that have a higher proportion of low socioeconomic status women, and have a higher proportion of women from racial and ethnic minority groups will participate in mammography at lower rates and have more cases of breast cancer diagnosed at an advanced state.

Study #: 50048
Title of Protocol: Correlation of SIDS and Pertussis Infection in Virginia
Principal Investigator: Denis M. Toney, Ph.D.
Date approved: December 30, 2007
Description of Study: This study will assess the possible correlations between sudden infant death syndrome and pertussis infections in Virginia.

Study #: 50049
Title of Protocol: Pandemic Influenza Preparedness Community Assessment
Principal Investigator: Liane Sowinski, MS
Date approved: August 7, 2007
Description of Study: This study will assess the knowledge gaps and preparedness needs regarding pandemic influenza in a community. Study results will be used to help health district staff prioritize public education activities.

Study #: 50050
Title of Study: Maternal Mortality Review Team
Principal Investigator: Victoria M. Kavanaugh, Ph.D.
Date approved: October 22, 2007
Description of Study: This study assesses all deaths in Virginia to women occurring during a pregnancy or within one year of the termination of a pregnancy to better understand the causes of death. Study results will be used to recommend changes and/or improvements to laws and/or practices and to identify interventions that could reduce the number of preventable maternal deaths.

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 2007		
Committee Members	Qualifications for Service	Institutional Affiliation
IRB CHAIR		
Kathy H. Wibberly	Ph.D. in Counseling Psychology & Policy Advisor in Office of Health Policy and Planning (recently renamed Office of Minority Health and Public Health Policy)	Virginia Department of Health
VOTING MEMBERS		
Rene S. Cabral-Daniels (resigned March 2007)	J.D., M.P.H. & Director, Office of Health Policy and Planning (recently renamed Office of Minority Health and Public Health Policy)	Virginia Department of Health
Carrie B. Dolan (appointment began September 2006)	M.P.H. in Epidemiology & Epidemiologist	Virginia Department of Health
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
Edward L. Van Oeveren (inactive, on military leave beginning August 2006)	J.D., M.D., M.P.H. & Director, West Piedmont Health District	West Piedmont Health District
Jessica L. Waugh	M.A. in Religious Studies (Ethics/Bioethics)	Independent Contractor, Editorial and Writing Services
ALTERNATE MEMBERS		
Ana Lizzette Colon (appointment began December 2006)	M.P.H. in Epidemiology & Regional Surveillance Coordinator	Virginia Department of Health, Eastern Region Field Office
Vacant	N/A	N/A