

**REPORT TO THE COMMISSIONER:  
ACTIVITIES OF THE VDH IRB FOR  
CALENDAR YEAR 2006**

**Submitted by**

**Kathy H. Wibberly, Ph.D.  
Chair, VDH IRB**

**REPORT TO THE COMMISSIONER:  
ACTIVITIES OF THE VDH IRB FOR CALENDAR YEAR 2006**

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) here 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 (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.

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 2006.

**I. A description of each human research project reviewed and approved or disapproved:**

**A. Full Board Reviews**

None.

**B. Expedited Reviews:**

<b>Study #:</b>	40058
<b>Principal Investigator:</b>	Craig Slingluff, M.D.
<b>Title of Protocol:</b>	"Desmoplastic Melanoma: A Clinicopathologic Study"
<b>Date approved:</b>	January 3, 2006
<b>Description of Study:</b>	This study compares specimens diagnosed as desmoplastic melanoma, neurotropic melanoma or spindle cell melanoma from the surgical pathology archives with reviews of patient charts, UVA's cancer registry, and the Virginia Cancer Registry to calculate disease-specific overall survival, disease-free survival, frequency of lymph node involvement, frequency of distant metastasis, and local recurrence rates for each of the melanoma categories. The data will also be compared with a control group of randomly selected, age-matched patients with conventional melanoma. Provided the data show differences among the melanoma categories, analyses will be run to determine if melanoma histologic sub-type is an independent prognostic variable.

**Study #:** 40061  
**Principal Investigator:** Katrina Armstrong, M.D., MSCE  
**Title of Protocol:** “Segregation and Racial Disparities in Prostate Cancer”  
**Date approved:** February 10, 2006  
**Description of Study:** This NCI funded multi-state study examines existing disparities in prostate cancer treatment and survival between Black and White men by considering the contribution of the social environment, particularly socioeconomic deprivation, residential segregation, neighborhood resources and access to medical care. Treatment information from claims data for men who are Medicare beneficiaries will be linked with Cancer Registry data as one component of the study. It is hypothesized that residential segregation correlates with worse prostate cancer outcomes among Black men, that the effect of segregation contributes to racial disparities in outcomes and that this effect is mediated, in part, through differential use of low quality hospitals and providers.

**Study #:** 40062  
**Principal Investigator:** Ann Nichols-Casebolt, Ph.D.  
**Title of Protocol:** “Constraints on the Breastfeeding Choices of Low-Income Mothers”  
**Date approved:** February 10, 2006  
**Description of Study:** This study examines breastfeeding constraints felt by a sample of mothers served by the WIC program in a central region of Virginia. It is hypothesized that: 1) mothers who perceive higher levels of social support for breastfeeding will have higher breastfeeding initiation and duration rates; 2) mothers who need to spend greater time apart from their infants for work will have lower breastfeeding initiation and duration rates; and 3) mothers who have increased sexual perceptions of breastfeeding will have lower breastfeeding initiation and duration rates.

**Study #:** 40063  
**Principal Investigator:** James Hersey, Ph.D. and Lucia Rojas Smith, Dr. PH  
**Title of Protocol:** “Assessment of State Early Hearing Detection and Intervention Programs (EHDI): A Program Operations Evaluation”  
**Date approved:** February 14, 2006  
**Description of Study:** This study, sponsored by the CDC, intends to evaluate the effectiveness of Early Hearing Detection and Intervention Programs in five states. The study will identify and examine the barriers and factors that contribute to loss to follow-up, and then develop strategies to reduce such loss.

**Study #:** 40064  
**Principal Investigator:** Gary M. Marsh, Ph.D.  
**Title of Protocol:** “Epidemiology and Biostatistical Component of the Pratt & Whitney Cohort Mortality and Cancer Incidence Study”  
**Date approved:** April 11, 2006  
**Description of Study:** This historical cohort mortality study compares the number of observed brain cancer deaths to the expected number among employees of the Pratt and Whitney aircraft engine manufacturing company in Connecticut. The study originated as an investigation by the state health department of a suspected cancer cluster in one of the plants in North Haven.

**Study #:** 40065  
**Principal Investigator:** Allen Lewis, Ph.D.  
**Title of Protocol:** "Evaluation of the STOP- DAT Teenage Pregnancy Prevention Program"  
**Date approved:** May 4, 2006  
**Description of Study:** This study evaluates a teen pregnancy prevention program conducted by the International Black Women's Congress using a pre-post test and comparison group design.

**Study #:** 40067  
**Principal Investigator:** Jody Lynne Stones  
**Title of Protocol:** "Healthy Native Living Project"  
**Date approved:** June 23, 2006  
**Description of Study:** This study attempts to determine if traditional, culturally appropriate interventions will change two Native Virginia tribal communities' cardio-vascular disease risk. The focus of the intervention will be on increasing consumption of traditional healthy foods and participating in traditional physical activities. A control group will be used.

**Study #:** 40068  
**Principal Investigator:** Dena Bensen, MPH  
**Title of Protocol:** "Medical Monitoring Project 2006 Protocol"  
**Date approved:** August 23, 2006  
**Description of Study:** This is a CDC funded national population surveillance study to assess the clinical outcomes, behaviors and the quality of care for people living with HIV.

**Study #:** 40069  
**Principal Investigator:** Janice Hicks  
**Title of Protocol:** "Virginia Pregnancy Risk Assessment Monitoring System (VA-PRAMS)"  
**Date approved:** September 25, 2006  
**Description of Study:** This is a CDC funded surveillance study of maternal attitudes and experiences before, during and shortly after pregnancy. The data will be used to identify groups of women and infants at high risk for health problems, to monitor changes in health status and to measure progress towards goals in improving the health of mothers and infants.

**Study #:** 40070  
**Principal Investigator:** Patricia C. Juliao, Ph.D., MPH  
**Title of Protocol:** "Salmonella Newport and Javiana Case-Control Study in the Eastern Region of Virginia"  
**Date approved:** October 6, 2006  
**Description of Study:** This is a case-control study of exposure risk factors among residents in the eastern part of Virginia who have been infected with Salmonella (Newport and Javiana strains). The purpose of the study is to examine the reasons for a rise in rates of salmonella infections over the past five years in the region.

**Study #:** 40071  
**Principal Investigator:** Debra Perina, M.D.  
**Title of Protocol:** "Trends in Motorcycle Crashes in Virginia"  
**Date approved:** October 19, 2006  
**Description of Study:** This study will document trends in the number and characteristics of motorcycle crashes in Virginia, identify long-term and short-term medical consequence and costs associated with them, and describe current motorcycle crash problems in order to improve public awareness and influence public policy regarding motorcycle safety.

**Study #:** 40072  
**Principal Investigator:** Debra Perina, M.D.  
**Title of Protocol:** "An Investigation of the Impact of Guardrail Type and Vehicle Classification on Crash Severity"  
**Date approved:** October 18, 2006  
**Description of Study:** This study will examine Virginia Department of Transportation and Virginia Trauma Registry data to identify Sport Utility Vehicle (SUV) crash characteristics and problems in comparison to other vehicle types. The study will look specifically at whether guardrail crash rates for SUVs are over-represented and whether guardrail standards should be changed.

**Study #:** 40074  
**Principal Investigator:** Catherine McManus  
**Title of Protocol:** "Serologic Survey for Brucella Antibodies Among Personnel Involved in the Depopulation of Brucella suis-positive Feral Hogs in Two Shooting Enclosures in Central Virginia"  
**Date approved:** December 20, 2006  
**Description of Study:** This study will use a combination of serology and questionnaire research to determine if personnel involved in the depopulation of Brucella suis- positive feral hogs in two shooting enclosures in central Virginia were exposed to Brucella and will also attempt to identify risk factors for exposure to brucellosis.

### C. Exemption Reviews

**Study #:** 50033  
**Principal Investigator:** Jennifer Ann Morrow  
**Title of Protocol:** "Adolescent Sexual Attitudes and Behavior: How Important is Parent Communication and Involvement?"  
**Date approved:** February 22, 2006  
**Description of Study:** This study will examine the familial system as it relates to adolescent sexual attitudes and behavior. Family process, structure and demographic variables will be examined, with a particular emphasis on parent-adolescent communication, parental monitoring, parental attitudes about adolescent sexual activity, and demographics as predictors of adolescent sexual attitudes and behavior.

**Study #:** 50034  
**Principal Investigator:** Elizabeth E. Turf  
**Title of Protocol:** "A Community Profile for the Richmond, VA Affiliate of the Susan G. Komen Breast Cancer Foundation"  
**Date approved:** February 22, 2006  
**Description of Study:** This study will look at existing data on breast health and breast cancer in order to determine needs in the Richmond area. The results of the study will be used to identify specific populations within the service area that are most in need of breast health services or that suffer disproportionately from breast cancer in order to prioritize funding and services.

**Study #:** 50035  
**Principal Investigator:** Han Kang  
**Title of Protocol:** "Estimates of Cancer Prevalence in Gulf Veterans Using State Registries"  
**Date approved:** March 23, 2006  
**Description of Study:** This study will test the hypothesis that deployment to the Persian Gulf in 1990- 1991 is associated with an increased incidence of specific malignancies. Specifically, the study will assess the relative incidence, distribution and characteristics of cancer among Gulf War veterans and non-Gulf War veterans and then to assess demographic, military and in-theater exposure characteristics associated with the cancer.

**Study #:** 50036  
**Principal Investigator:** Sheanita Carter  
**Title of Protocol:** "Resolving Workplace Conflict: A Path to Higher Morale"  
**Date approved:** March 27, 2006  
**Description of Study:** This study will look at the causes of workplace conflict, examine how unresolved conflict impacts employee morale, and use findings to identify strategies for addressing unresolved workplace conflict.

**Study #:** 50037  
**Principal Investigator:** Michelle White  
**Title of Protocol:** "Commonwealth of VA Child and Adolescent Injury Survey"  
**Date approved:** March 30, 2006  
**Description of Study:** This study will gather data regarding attitudes, knowledge and safety practices related to childhood and adolescent injury and test the hypothesis that there will be differences between households with children and adolescents and those without.

**Study #:** 50038  
**Principal Investigator:** James Randall Davidson  
**Title of Protocol:** "Resolving Leveling the Playing Field for Parents: Understanding the Individual Education Plan"  
**Date approved:** March 30, 2006  
**Description of Study:** This study will examine the degree educating parents about the Individual Education Plan (IEP) process impacts parent understanding and participation in the process.

**Study #:** 50039  
**Principal Investigator:** Mary I. Young, M.D.  
**Title of Protocol:** "The Women's Interagency HIV Study (WIHS)"  
**Date approved:** July 13, 2006  
**Description of Study:** This multicenter longitudinal study funded by the NIH investigates the progression and impact of HIV infection in women

**Study #:** 50040  
**Principal Investigator:** Judith Bradford, Ph.D.  
**Title of Protocol:** "Evaluation of Virginia Department of Health Family Planning Clinics"  
**Date approved:** October 17, 2006  
**Description of Study:** This focus group study investigates the reasons for underutilization of family planning clinics by low-income women and to determine if there are any actions that VDH could take to overcome any barriers to utilization.

**Study #:** 50041  
**Principal Investigator:** Ian McCutcheon, M.D. and Ganesh Rao, M.D.  
**Title of Protocol:** "Meningioma in Men"  
**Date approved:** October 18, 2006  
**Description of Study:** This retrospective study investigates the association between breast cancer and meningioma in men.

**Study #:** 50042  
**Principal Investigator:** Susan Kennedy Spain  
**Title of Protocol:** "Behavioral Risk Factor Surveillance System State-Added Questions 2007"  
**Date approved:** December 18, 2006  
**Description of Study:** This study entails the addition of state-added questions to the CDC Behavioral Risk Factor Surveillance System standard protocol. These questions include modules related to suicide, residential fire, sexual violence, intimate partner violence, secondhand smoke policy, smoking cessation, adult asthma history, random child selection, childhood asthma prevalence, oral health, diabetes, immunization, mental illness and stigma, heart attack and stroke, workplace smoking, skin cancer/excess sun and arthritis management.

**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.

<b>VDH IRB 2006</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 & Policy Advisor in Office of Health Policy and Planning (recently renamed Office of Minority Health and Public Health Policy).	Virginia Department of Health
<b>VOTING MEMBERS</b>		
Rene S. Cabral-Daniels	J.D., M.P.H. & Director, Office of Health Policy and Planning	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
H. Dennis Kade (resigned September 2006)	Ph.D. in Clinical Psychology & Psychology Supervisor	Norfolk Department of Public Health and Tidewater Child Development Services
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
<b>ALTERNATE MEMBERS</b>		
Ana Lizzette Colon (appointment began December 2006)	M.P.H. in Epidemiology & Regional Surveillance Coordinator	Virginia Department of Health, Eastern Region Field Office
Carrie B. Dolan (appointment began September 2006)	M.P.H. in Epidemiology & Epidemiologist	Virginia Department of Health



**Virginia Department of Health  
Institutional Review Board**

**MINUTES**

**January 4, 2006**

**10:30 AM – 1:00 PM**

**Members Present:** Kathy Wibberly (Chair), Rene Cabral-Daniels, Bethany Geldmaker, Gail Jennings, Dennis Kade, Ed Van Oeveren, Jessica Waugh

**Members Absent:** Greg Stolcis

**Guests:** None

**General Items/Announcements:**

- ◆ The meeting convened at 10:43 AM. A quorum was present.
- ◆ Rene did a search on LEXIS and was unable to find any reported federal cases related to the NIH Certificate of Confidentiality. The only such certificates of confidentiality in the case law involved the Federal Trade Commission certificates. Ed did some research at the NIH website and reported that these certificates are used to protect identifiable research information from forced disclosure in the event of a legal/court related proceeding where disclosure could have adverse consequences for research subjects. There have been very few reported court cases. In 1973, the certificate's authority was upheld in the New York Court of Appeals. The U.S. Supreme Court declined to hear the case. This Certificate can be applied for by any researcher working with collection of sensitive data/information. For more information visit the NIH website at <http://grants1.nih.gov/grants/policy/coc/>
- ◆ A public comment draft of the CDC Health Protection Research Guide, 2006 – 2015 was disseminated on November 18, 2005. Public comments are due to CDC next week.
- ◆ Joint training event opportunity with DRS for 2006 – being proposed are case-based/what-if scenarios. Other ideas/thoughts?
  - Recommend that we look through old meeting minutes to identify topics of discussion that have come up on more than one occasion
  - Cultural sensitivity issues in research
  - Handling poorly written protocols
  - Surveillance versus research
  - Use of databases and ownership
  - Computer security and data transport issues
  - Readability and informed consent issues
  - Working with federal and interagency agreements and approvals
- ◆ Minutes from the October meeting were unanimously approved.

**Meeting dates/schedule for 2006**

- ◆ Monday, April 3
- ◆ Monday, July 10
- ◆ Monday, October 2

For all dates, please keep the block of time between 10AM – 1PM open. Meetings will generally begin at 10:30AM and end by 12:30PM, but we need to allow for extra time in case we have a heavy load.

**PRESENTATION OF NEW PROTOCOLS - EXEMPTION REVIEW:**

**Study #:** 50031  
**Principal Investigator:** Linda Birtley  
**Title of Protocol:** “Teen Pregnancy Prevention Initiative Program Evaluation: Investigation of Barriers to Program Evaluation and Utilization of Evaluation Results”  
**Primary Reviewer:** Rene Cabral-Daniels  
**Discussion:** None.  
**Description of Action:** Approved unanimously (one abstention)

**Study #:** 50032  
**Principal Investigator:** Susan Kennedy Spain  
**Title of Protocol:** “Behavioral Risk Factor Surveillance System State-Added Questions 2006”  
**Primary Reviewer:** Rene Cabral-Daniels  
**Discussion:** None.  
**Description of Action:** Approved.

**PRESENTATION OF NEW PROTOCOLS - EXPEDITED REVIEW:**

**Study #:** 40058  
**Principal Investigator:** Craig Slingsluff, M.D.  
**Title of Protocol:** “Desmoplastic Melanoma: A Clinicopathologic Study”  
**Primary Reviewer:** Ed VanOeveren  
**Discussion:** None.  
**Description of Action:** Approved unanimously.

**Study #:** 40059  
**Principal Investigator:** John Bruce McClain, M.D.  
**Title of Protocol:** “Collection of Blood Specimens for Tissue Sample Bank to Support Shipping Validation and Tuberculosis Assay Validation”  
**Primary Reviewer:** Bethany Geldmaker  
**Discussion:** None.  
**Description of Action:** Approved unanimously.

**Study #:** 40060  
**Principal Investigator:** Karen C. Day  
**Title of Protocol:** “1999 Virginia Statewide Oral Health Needs Assessment”  
**Primary Reviewer:** Rene Cabral-Daniels  
**Discussion:** None.  
**Description of Action:** Approved unanimously.

**PRESENTATION OF INITIAL SUBMISSIONS - FULL BOARD REVIEW:**

None

**CONTINUATION REVIEWS/RENEWALS:**

**Study #:** 30001  
**Principal Investigator:** Gale E. Grant, M.A., C.P.P.  
**Title of Protocol:** "Evaluation of the Virginia Abstinence Education Initiative"  
**Discussion:** None.  
**Description of Action:** Approved unanimously (one abstention)

**Study #:** 30004  
**Principal Investigator:** Casey W. Riley  
**Title of Protocol:** "Behavioral Risk Assessment Survey of STD Clinic Attendees"  
**Discussion:** None.  
**Description of Action:** Study closed.

**Study #:** 40002  
**Principal Investigator:** Eugenia E. Calle, Ph.D.  
**Title of Protocol:** "Follow-up of CPS-II Participants through Linkage with State Cancer Registries."  
**Discussion:** None.  
**Description of Action:** Approved unanimously.

**Study #:** 40003  
**Principal Investigator:** Gary M. Marsh, Ph.D.  
**Title of Protocol:** "Cohort Mortality and Cancer Incidence Studies of the Stonewall, VA Facility"  
**Discussion:** None.  
**Description of Action:** Study closed.

**Study #:** 40005  
**Principal Investigator:** M. Norman Oliver, M.D.  
**Title of Protocol:** "Role of Environment and Diet in Increased Prostate Cancer Mortality in African Americans"  
**Discussion:** None.  
**Description of Action:** Approved unanimously.

**Study #:** 40007  
**Principal Investigator:** Pauline Terebuh, M.D., MPH and Akinyi Adija, M.D.  
**Title of Protocol:** "A Study of the Prevalence of Avian Influenza A Virus Antibodies in Persons Participating in Operations to Detect and Control the Outbreak of Influenza A (H7N2) Among Poultry in Virginia, 2002"  
**Discussion:** None.  
**Description of Action:** Study closed.

**Study #:** 40010  
**Principal Investigator:** Delores Dungee-Anderson, Ph.D.  
**Title of Protocol:** "An Analysis of the Impact Health Information and Health Information Venues Have on Periodic Screening Outcomes Among African-American Women"  
**Discussion:** None.  
**Description of Action:** Study closed.

**Study #:** 40011  
**Principal Investigator:** Pauline Terebuh, M.D., MPH and Akinyi Adija, M.D.  
**Title of Protocol:** “A study to determine the seroprevalence of antibodies to avian and human influenza A viruses in workers occupationally exposed to poultry in Virginia, 2002”  
**Discussion:** None.  
**Description of Action:** Study closed.

**Study #:** 40015  
**Principal Investigator:** Louise Wideroff, Ph.D.  
**Title of Protocol:** “Family Health Study (Validation of a Family History of Cancer Questionnaire for Risk Factor Surveillance)”  
**Discussion:** There was interest in finding out from the P.I. how many of the participants were part of WIC (response: 62 WIC participants were eligible to participate and 40 completed the questionnaires).  
**Description of Action:** Approved unanimously.

**Study #:** 40024  
**Principal Investigator:** Rachel K. Jones  
**Title of Protocol:** “Parental Engagement Among Adolescents Using Clinic-Based Reproductive Health Services”  
**Discussion:** None.  
**Description of Action:** Approved unanimously

**Study #:** 40029  
**Principal Investigator:** James Hersey, Lucia Rojas Smith, and Pamela Costa  
**Title of Protocol:** “Assessment of State Early Hearing Detection and Intervention Programs (EHDI): A Program Operations Evaluation”  
**Discussion:** PI submitted case closure agreement from CDC which did not require any kind of study summary. PI will be asked to submit appropriate VDH forms.  
**Description of Action:** Study will be closed pending receipt of proper documentation.

**Study #:** 40047  
**Principal Investigator:** Tejpratap Tiwari, M.D.  
**Title of Protocol:** “Risk Factors for Mortality Due to Pertussis Among Infants in the U.S. – A Case Control Study”  
**Discussion:** None.  
**Description of Action:** Approved unanimously

**Study #:** 40048  
**Principal Investigator:** Anneke Schroen  
**Title of Protocol:** “The Impact of Mammography Access on Breast Cancer Tumor Size at Diagnosis”  
**Discussion:** None.  
**Description of Action:** Approved unanimously

**Study #:** 40049  
**Principal Investigator:** John Ambrose, MPH, CHES  
**Title of Protocol:** “Evaluation of Timely Communicable Disease Reporting by Local Providers in a Rural Virginia Health District”  
**Discussion:** None.  
**Description of Action:** Study closed.

**OTHER (MINOR MODIFICATIONS, ETC):**

**Study #:** 40051  
**Principal Investigator:** Jennifer Ann Morrow, Ph.D.  
**Title of Protocol:** “Evaluation of the Talk2Me Toolkit”  
**Type of Review:** **Minor Modification Request**  
**Description:** Extension of project period to May 2006 due to delays in data collection.  
**Discussion:** None.  
**Description of Action:** Approved unanimously (one abstention)

Meeting was adjourned at 12:35 PM.

**Virginia Department of Health  
Institutional Review Board**

**MINUTES**

**April 3, 2006  
10:30 AM – 12:30 PM**

**Members Present:** Kathy Wibberly (Chair), Rene Cabral-Daniels, Bethany Geldmaker, Dennis Kade, Ed Van Oeveren, Jessica Waugh

**Members Absent:** Gail Jennings, Greg Stolcis

**Guests:** None

**General Items/Announcements:**

- ◆ The meeting convened at 10:43 AM. A quorum was present.
- ◆ Minutes from the January meeting were unanimously approved.

**Meeting dates/schedule for 2006**

- ◆ Tuesday, July 11
- ◆ Monday, October 2

For all dates, please keep the block of time between 10AM – 1PM open. Meetings will generally begin at 10:30AM and end by 12:30PM, but we need to allow for extra time in case we have a heavy load.

**PRESENTATION OF NEW PROTOCOLS - EXEMPTION REVIEW:**

**Study #:** 50033  
**Principal Investigator:** Jennifer Ann Morrow  
**Title of Protocol:** “Adolescent Sexual Attitudes and Behavior: How Important is Parent Communication and Involvement?”  
**Primary Reviewer:** Bethany Geldmaker  
**Discussion:** Initial application was sent back for re-writes due to multiple typographical errors and a paucity of information. Resubmission was improved in quality and content.  
**Description of Action:** Unanimously Approved.

**Study #:** 50034  
**Principal Investigator:** Elizabeth E. Turf  
**Title of Protocol:** “A Community Profile for the Richmond, VA Affiliate of the Susan G. Komen Breast Cancer Foundation”  
**Primary Reviewer:** Jessica Waugh  
**Discussion:** None.  
**Description of Action:** Unanimously Approved.

**Study #:** 50035  
**Principal Investigator:** Han Kang  
**Title of Protocol:** “Estimates of Cancer Prevalence in Gulf Veterans Using State Registries”

**Primary Reviewer:** Ed Van Oeveren  
**Discussion:** None.  
**Description of Action:** Unanimously Approved.

**Study #:** 50036  
**Principal Investigator:** Sheanita Carter  
**Title of Protocol:** “Resolving Workplace Conflict: A Path to Higher Morale”  
**Primary Reviewer:** Rene Cabral Daniels  
**Discussion:** None.  
**Description of Action:** Unanimously Approved.

**Study #:** 50037  
**Principal Investigator:** Michelle White  
**Title of Protocol:** “Commonwealth of VA Child and Adolescent Injury Survey”  
**Primary Reviewer:** Dennis Kade  
**Discussion:** Although reading level check in MS Word calculated the survey instrument at a 5<sup>th</sup> grade reading level, it was primarily due to the short sentence structure of the survey questions. When individual paragraphs were checked (including the consent form), they came out to be at a much higher reading level.  
**Description of Action:** Unanimously Approved.

**Study #:** 50038  
**Principal Investigator:** James Randall Davidson  
**Title of Protocol:** “Resolving Leveling the Playing Field for Parents: Understanding the Individual Education Plan”  
**Primary Reviewer:** Bethany Geldmaker  
**Discussion:** Discussion centered around this intervention as being a good first step in addressing the issues, however it is unclear whether an educational intervention would actually lead to parental advocacy is unclear.  
**Description of Action:** Unanimously Approved.

#### **PRESENTATION OF NEW PROTOCOLS - EXPEDITED REVIEW:**

**Study #:** 40061  
**Principal Investigator:** Katrina Armstrong, M.D., MSCE  
**Title of Protocol:** “Segregation and Racial Disparities in Prostate Cancer”  
**Primary Reviewer:** Gail Jennings  
**Discussion:** This was a well written protocol. Surprising, it lacked a standard few written assurances that needed to be requested before approval could be granted (e.g., assurance that dataset would not be made available to the public and that data suppression rules applied for small cell sizes).  
**Description of Action:** Unanimously Approved.

**Study #:** 40062  
**Principal Investigator:** Ann Nichols-Casebolt, Ph.D.  
**Title of Protocol:** “Constraints on the Breastfeeding Choices of Low-Income Mothers”  
**Primary Reviewer:** Rene Cabral-Daniels  
**Discussion:** None.  
**Description of Action:** Unanimously Approved.

**Study #:** 40063  
**Principal Investigator:** James Hersey, Ph.D. and Lucia Rojas Smith, Dr. PH  
**Title of Protocol:** “Assessment of State Early Hearing Detection and Intervention Programs (EHDI): A Program Operations Evaluation”  
**Primary Reviewer:** Greg Stolcis  
**Discussion:** None.  
**Description of Action:** Unanimously Approved.

**PRESENTATION OF INITIAL SUBMISSIONS - FULL BOARD REVIEW:**

None

**CONTINUATION REVIEWS/RENEWALS:**

**Study #:** 40014  
**Principal Investigator:** Mena Forrester, M.D., R.D..  
**Title of Protocol:** “Third Study of the Nutritional Status of Fourth-Grade Children”  
**Discussion:** None.  
**Description of Action:** Unanimously Approved.

**OTHER (MINOR MODIFICATIONS, ETC):**

**Study #:** 40063  
**Principal Investigator:** James Hersey, Ph.D. and Lucia Rojas Smith, Dr. PH  
**Title of Protocol:** “Assessment of State Early Hearing Detection and Intervention Programs (EHDI): A Program Operations Evaluation”  
**Modification Request:** In the originally approved protocol, VDH was to send out letters to the mothers informing them about the study (general information, time frame, way to opt out of the study, and a copy of the informed consent form which would be read to them verbally by the CATI interviewers prior to survey administration). When the letters were sent out, a copy of the informed consent form was not sent with it. P.I. would like to modify the protocol so that the lead letter does not include a copy of the informed consent form instead of having to send out the forms under separate cover.  
**Discussion:** Verified that this is a phone survey and that respondents are read the consent form orally via telephone. Also verified that the letter does not indicate that a copy of the consent form was to be included, hence not having the paper copy of the consent form was not deemed to be a problem or potential source of confusion.  
**Description of Action:** Unanimously Approved.

Meeting was adjourned at 11:45 PM.



**Virginia Department of Health  
Institutional Review Board**

**MINUTES**

**July 11, 2006  
10:30 AM – 12:30 PM**

**Members Present:** Kathy Wibberly (Chair), Bethany Geldmaker, Gail Jennings, Ed Van Oeveren, Greg Stolcis Jessica Waugh

**Members Absent:** Rene Cabral-Daniels, Dennis Kade

**Guests:** None

**General Items/Announcements:**

- ◆ The meeting convened at 10:41 AM. A quorum was present.
- ◆ Minutes from the April meeting were unanimously approved.
- ◆ Ed Van Oeveren has been called up for 12 months of military service at Fort Knox and will be leaving this weekend.

**Meeting dates/schedule for 2006**

- ◆ Monday, October 2 (please keep the block of time between 10AM – 1PM open. Meetings will generally begin at 10:30AM and end by 12:30PM, but we need to allow for extra time in case we have a heavy load)
  - Please bring your calendars to our next meeting in order to set dates for 2007.

**PRESENTATION OF NEW PROTOCOLS - EXEMPTION REVIEW:**

<b>Study #:</b>	50039
<b>Principal Investigator:</b>	Mary I. Young, M.D.
<b>Title of Protocol:</b>	“The Women’s Interagency HIV Study (WIHS)”
<b>Primary Reviewer:</b>	Rene Cabral-Daniels
<b>Discussion:</b>	Rene had requested two points of clarification during the initial review. Clarification was provided, however, copies of approval letters from reviews by other IRBs were not provided. These will be requested from the P.I.
<b>Description of Action:</b>	Unanimously Approved – Documentation of Approvals from Other IRBs required.

Bethany Geldmaker arrived at 11:00 AM during the discussion of this protocol.

**PRESENTATION OF NEW PROTOCOLS - EXPEDITED REVIEW:**

<b>Study #:</b>	40064
<b>Principal Investigator:</b>	Gary M. Marsh, Ph.D.
<b>Title of Protocol:</b>	“Epidemiology and Biostatistical Component of the Pratt & Whitney Cohort Mortality and Cancer Incidence Study”

**Primary Reviewer:** Gail Jennings  
**Discussion:** None.  
**Description of Action:** Unanimously Approved.

**Study #:** 40065  
**Principal Investigator:** Allen Lewis, Ph.D.  
**Title of Protocol:** "Evaluation of the STOP- DAT Teenage Pregnancy Prevention Program"  
**Primary Reviewer:** Rene Cabral-Daniels  
**Discussion:** None.  
**Description of Action:** Unanimously Approved.

**Study #:** 40066  
**Principal Investigator:** Heather L. Peters, Ph.D.  
**Title of Protocol:** "Cocaine-N-oxide Detection in Hair"  
**Primary Reviewer:** Ed Van Oeveren  
**Discussion:** This study protocol was incomplete lacked sufficient detail for an adequate review. PI has been asked to revise and resubmit.  
**Description of Action:** None.

**Study #:** 40067  
**Principal Investigator:** Jody Lynne Stones  
**Title of Protocol:** "Healthy Native Living Project"  
**Primary Reviewer:** Greg Stolcis  
**Discussion:** This study was methodologically sound. However, portions of the actual intervention were still under development, with a range of potential interventions listed. PI will be requested to submit an actual intervention plan as soon as it is developed. Only those interventions actually described in the submitted protocol are approved. If the intervention plan reflects changes from what was listed in the submitted protocol, those changes will require review as a minor modification.  
**Description of Action:** Unanimously Approved - Intervention Plan Required.

#### **PRESENTATION OF INITIAL SUBMISSIONS - FULL BOARD REVIEW:**

None

#### **CONTINUATION REVIEWS/RENEWALS:**

**Study #:** 30005  
**Principal Investigator:** Karen Day, DDS, MPH  
**Title of Protocol:** "Fluoride Varnish Study"  
**Discussion:** Minor modifications to protocol were discussed.  
**Description of Action:** Unanimously Approved.

Group took a brief break for lunch. Bethany Geldmaker left the meeting at this point.

**Study #:** 40016  
**Principal Investigator:** Melvin Wilson  
**Title of Protocol:** "Early Family Centered Prevention of Conduct Disorder and Drug Use"

**Discussion:** Risk in Rural Populations”  
**Description of Action:** None.  
 Unanimously Approved.

**Study #:** 40019  
**Principal Investigator:** Allen Lewis, Ph.D.  
**Title of Protocol:** “TPPI: Portsmouth – Becoming a Responsible Teen (BART) Project Outcome Evaluation Study”  
**Discussion:** None.  
**Description of Action:** Unanimously Approved.

**Study #:** 40021  
**Principal Investigator:** Allen Lewis, Ph.D.  
**Title of Protocol:** "Eastern Shore Teen Pregnancy Prevention Program: Young Voices for Better Choices"  
**Discussion:** None.  
**Description of Action:** Unanimously Approved.

**Study #:** 40022  
**Principal Investigator:** Allen Lewis, Ph.D.  
**Title of Protocol:** "Alexandria: Evaluation of Pro-Teen/Pro-Youth and Project Step Out Programs"  
**Discussion:** None.  
**Description of Action:** Unanimously Approved.

**Study #:** 40031  
**Principal Investigator:** Zandra Duprey, EISO  
**Title of Protocol:** “Mosquito control and pesticide exposure in North Carolina and Virginia”  
**Discussion:** None.  
**Description of Action:** Study completed/closed.

**Study #:** 40032  
**Principal Investigator:** Dr. Fred Angulo  
**Title of Protocol:** “Interview of persons from which enteric bacterial isolates have been cultured with uncommon antimicrobial resistance patterns”  
**Discussion:** None.  
**Description of Action:** Unanimously Approved.

**Study #:** 40037  
**Principal Investigator:** Gary M. Marsh, Ph.D.  
**Title of Protocol:** "The Cohort Mortality and Cancer Incidence Studies of the Rahway, NJ Facility"  
**Discussion:** None.  
**Description of Action:** Study completed/closed.

**Study #:** 40039  
**Principal Investigator:** Bridget J. McCarthy, Ph.D.  
**Title of Protocol:** "Central Brain Tumor Registry of the United States (CBTRUS)"  
**Discussion:** None.  
**Description of Action:** Unanimously Approved.

**Study #:** 40040  
**Principal Investigator:** Meir Stampfer, M.D., Dr. Ph.H.  
**Title of Protocol:** "Cohort Cancer Registry Follow-Up Study"  
**Discussion:** None.  
**Description of Action:** Unanimously Approved.

**Study #:** 40043  
**Principal Investigator:** Mitchell Holland  
**Title of Protocol:** "Collection Procedures for DNA Identification of John/Jane Does"  
**Discussion:** PI has been reported to OHRP for noncompliance with continuation review requirements and study has been suspended.  
**Description of Action:** Study suspended/closed.

**Study #:** 40050  
**Principal Investigator:** Kathy Orchen, B.S., P.A., MPH  
**Title of Protocol:** "Folic Acid Supplement Distribution Program"  
**Discussion:** None.  
**Description of Action:** Unanimously Approved.

**Study #:** 40052  
**Principal Investigator:** William Blot, Ph.D.  
**Title of Protocol:** "Southern Community Cohort Study (SCCS) Follow-Up Study for Cancer Incidence"  
**Discussion:** None.  
**Description of Action:** Unanimously Approved.

**Study #:** 40054  
**Principal Investigator:** Allen Lewis, Ph.D.  
**Title of Protocol:** "Crater: Evaluation of the Passport to Manhood Program"  
**Discussion:** None.  
**Description of Action:** Study completed/closed.

#### **OTHER (MINOR MODIFICATIONS, ETC):**

**Study #:** 30005  
**Principal Investigator:** Karen Day, DDS, MPH  
**Title of Protocol:** "Fluoride Varnish Study"  
**Modification Request:** For EHS interventions:

- Rather than using chart reviews to collect oral health information, a licensed dental provider will conduct the baseline and subsequent annual screenings for study participants enrolled in the EHS programs. Consent form has been revised to reflect this change.
- None of the screeners were blinded to the child's treatment status.
- None of the screeners were calibrated prior to the baseline exams, although the project coordinator performed many of the screenings.

- The one-year phase-in period for groups 2 and 3 (the initial two control groups) was shortened to a 6-month phase-in period. This will reduce the likelihood that newly enrolled participants at a designated “control” site will be exposed to the fluoride varnish treatment through the local health department/clinics. Health providers/staff at these facilities have received or will be receiving training to provide anticipatory guidance, conduct risk assessments and to apply fluoride varnish treatments for their patients. Furthermore, the reduced phase-in period will ensure that more of the older children assigned to the control groups will have an opportunity to receive the varnish treatment during the 3-year intervention.

The health department intervention, developed for targeting children enrolled in WIC programs (ages 0 – 5 years) has not been initiated and will probably be eliminated.

**Discussion:** Discussion centered around questions as to why the health department interventions were not being initiated. PI addressed this question in the continuation request narrative.

**Description of Action:** Unanimously Approved.

**Study #:** 40050

**Principal Investigator:** Kathy Orchen, B.S., P.A., MPH

**Title of Protocol:** "Folic Acid Supplement Distribution Program"

**Modification Request:** Change in P.I. from Kathy L. Orchen who will be leaving VDH to Nancy Ford. Enrollment will continue for 12 more months from the implementation month.

**Discussion:** None.

**Description of Action:** Unanimously Approved.

**Study #:** 40059

**Principal Investigator:** John Bruce McClain, M.D.

**Title of Protocol:** "Collection of Blood Specimens for Tissue Sample Bank to Support Shipping Validation and Tuberculosis Assay Validation"

**Modification Request:** For Spanish speaking subjects, instead of just having a Spanish version of the consent form, a video version of the Spanish informed consent form has been developed to assist subjects in their understanding of the study and in their decision making process regarding participation. Potential subjects are given the written informed consent to read and offered the video version should they so desire. Additionally, subjects have access to a telephone interpreter service. There are no changes to the content of the consent form other than two grammatical corrections. Subjects who view the video are still required to sign the consent document if they choose to enter the study.

**Discussion:** None.

**Description of Action:** Unanimously Approved.

Meeting was adjourned at 12:49 PM.

**Virginia Department of Health  
Institutional Review Board**

**MINUTES**

**October 2, 2006  
10:30 AM – 12:30 PM**

**Members Present:** Kathy Wibberly (Chair), Rene Cabral-Daniels, Carrie Dolan, Bethany Geldmaker, Gail Jennings, Greg Stolcis

**Members Absent:** Ed Van Oeveren, Jessica Waugh

**Guests:** None

**General Items/Announcements:**

- ◆ The meeting convened at 10:43 AM. A quorum was present.
- ◆ Membership:
  - New member: Carrie Dolan
  - Resignation: Dennis Kade
  - Recommendations for potential new members (local health district and external to VDH) needed
    - Suggestion: Curtis Thorpe
    - Recommendation: Someone to represent the Latino population
- ◆ Meeting dates/schedule for 2007
  - Monday, January 8 (Gail will likely be out on maternity leave on this date)
  - Monday, April 16
  - Monday, July 9
  - Monday, October 1
- ◆ Annual HRPP Conference – A Commitment to Ethical Research: Advancing the Mission of Human Research Protection Programs (November 15 – 18, 2006 at the Marriott Wardman Park Hotel, Washington, DC)
- ◆ Minutes from the July meeting were unanimously approved.

**PRESENTATION OF NEW PROTOCOLS - EXEMPTION REVIEW:**

<b>Study #:</b>	50040
<b>Principal Investigator:</b>	Judith Bradford, Ph.D.
<b>Title of Protocol:</b>	“Evaluation of Virginia Department of Health Family Planning Clinics”
<b>Primary Reviewer:</b>	Carrie Dolan
<b>Discussion:</b>	There was a missing attachment, a need to include contact information on the flyer and clarification needed regarding the consent process. These have been requested as conditions for approval of this protocol. Additionally, given the target population, a recommendation will be made to the P.I. to consider making available a Spanish translation of the consent form and having Spanish speaking interpreters available during the focus groups.
<b>Description of Action:</b>	Awaiting response from P.I. (response received and approved)
<b>Study #:</b>	50041

**Principal Investigator:** Ian McCutcheon, M.D. and Ganesh Rao, M.D.  
**Title of Protocol:** "Meningioma in Men"  
**Primary Reviewer:** Rene Cabral Daniels  
**Discussion:** There was a missing attachment, a need to include contact information on the flyer and clarification needed regarding the consent process. These have been requested as conditions for approval of this protocol. Additionally, given the target population, a recommendation will be made to the P.I. to consider making available a Spanish translation of the consent form and having Spanish speaking interpreters available during the focus groups.  
**Description of Action:** Awaiting response from P.I. (response received and approved)

**PRESENTATION OF NEW PROTOCOLS - EXPEDITED REVIEW:**

**Study #:** 40068  
**Principal Investigator:** Dena Bensen, MPH  
**Title of Protocol:** "Medical Monitoring Project 2006 Protocol"  
**Primary Reviewer:** Bethany Geldmaker  
**Discussion:** None.  
**Description of Action:** Unanimously Approved.

**Study #:** 40069  
**Principal Investigator:** Janice Hicks  
**Title of Protocol:** "Virginia Pregnancy Risk Assessment Monitoring System (VA-PRAMS)"  
**Primary Reviewer:** Rene Cabral-Daniels  
**Discussion:** None.  
**Description of Action:** Unanimously Approved.

**Study #:** 40070  
**Principal Investigator:** Patricia C. Juliao, Ph.D., MPH  
**Title of Protocol:** "Salmonella Newport and Javiana Case-Control Study in the Eastern Region of Virginia"  
**Primary Reviewer:** Gail Jennings

**Study #:** 40071  
**Principal Investigator:** Debra Perina, M.D.  
**Title of Protocol:** "Trends in Motorcycle Crashes in Virginia"  
**Primary Reviewer:** Greg Stolcis

**PRESENTATION OF INITIAL SUBMISSIONS - FULL BOARD REVIEW:**  
None

**CONTINUATION REVIEWS/RENEWALS:**

Gail left the room briefly at this point.

**Study #:** 30003  
**Principal Investigator:** Karen Day  
**Title of Protocol:** "Evaluation of a School Based Fluoride Rinse Program"  
**Discussion:** None.  
**Description of Action:** Unanimously Approved.

Gail returned to the room.

**Study #:** 40006  
**Principal Investigator:** Shelia P. Greenlee, Ph.D.  
**Title of Protocol:** "Evaluation of Very Important Person (VIP) Abstinence Education Program"  
**Discussion:** None.  
**Description of Action:** Study completed/closed.

**Study #:** 40027  
**Principal Investigator:** Fern Hauck, MD  
**Title of Protocol:** "Cross-Cultural Infant Care Practices in Virginia"  
**Discussion:** None.  
**Description of Action:** Unanimously Approved.

**Study #:** 40040  
**Principal Investigator:** Meir Stampfer, M.D., Dr. Ph.H.  
**Title of Protocol:** "Cohort Cancer Registry Follow-Up Study"  
**Discussion:** None.  
**Description of Action:** Unanimously Approved.

**Study #:** 40051  
**Principal Investigator:** Jennifer A. Morrow, Ph.D.  
**Title of Protocol:** "Talk2Me Toolkit Evaluation"  
**Discussion:** None.  
**Description of Action:** Study completed/closed.

Carrie left the room briefly during this discussion.

**Study #:** 40053  
**Principal Investigator:** Dawn M. Wesson, Ph.D.  
**Title of Protocol:** "West Nile Virus Infection and Outcomes of Pregnancy in Humans"  
**Discussion:** None.  
**Description of Action:** Unanimously Approved.

**OTHER (MINOR MODIFICATIONS, ETC):**

None

Meeting was adjourned at 12:09 PM.