

REPORT TO THE COMMISSIONER:

**ACTIVITIES OF THE VIRGINIA
DEPARTMENT OF HEALTH INSTITUTIONAL
REVIEW BOARD FOR CALENDAR YEAR
2008**

Submitted by

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

**REPORT TO THE COMMISSIONER:
ACTIVITIES OF THE VDH IRB FOR CALENDAR YEAR 2008**

The Virginia's State Board of Health's regulations for the conduct of human research 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 must 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 (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 makes formal 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 2008.

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

A. Full Board Reviews

None.

B. Expedited Reviews:

Study #:	40085
Title of Study:	Nursing Home Oral Health Intervention
Principal Investigator:	Karen C. Day
Date approved:	February 26, 2008
Description of Study:	This longitudinal study of nursing home residents will evaluate the effectiveness of a six-month oral health intervention utilizing a nurse's aide for the provision of dental care/services to long-term care residents in two facilities in Virginia. Results of the study will be used to determine whether the nurse's aide intervention could or should be replicated in other long-term care facilities across the state.

Study #: 40086
Title of Study: Oral Health Assessment of Virginia Elders
Principal Investigator: Karen C. Day
Date approved: March 3, 2008
Description of Study: This study will assess the oral health of elder populations (age 65 years and older), including nursing home residents, homebound seniors, elders who attend senior congregates and assisted living residents. A geographically representative sampling will be obtained from each of Virginia's five health planning regions

Study #: 40087
Title of Study: Richmond Region WIC Oral Health Intervention
Principal Investigator: Karen C. Day
Date approved: January 15, 2008
Description of Study: This study will evaluate the effectiveness of the oral health intervention (dental screenings, fluoride varnish applications and anticipatory guidance) provided to WIC enrolled children and pregnant women in the Richmond metropolitan area.

Study #: 40088
Title of Study: Prehospital Patient Triage in Mass Casualty Incidents: An Engineering Management Analysis and Strategy
Principal Investigator: John Harrald, Ph.D.
Date approved: March 7, 2008
Description of Study: This study will assess the effectiveness and impact of expanding the Simple Triage and Rapid Treatment (START) system to include more medical criteria mechanisms of injury. START is a prehospital casualty triage system used by emergency medical technicians.

Study #: 40089
Title of Study: Hampton Roads VDH/VIMS Clam Project
Principal Investigator: Howard Kator, Ph.D.
Date approved: June 9, 2008
Description of Study: This study will explore techniques for analyzing clams from Hampton Roads for norovirus, with the anticipated goal of developing a technique that can be used as a laboratory standard.

Study #: 40090
Title of Study: Barriers to Behavioral Health Care in Rural Virginia
Principal Investigator: Wendy Kliewer, Ph.D.
Date approved: June 10, 2008
Description of Study: This study will assess behavioral health services in two rural regions in Virginia. The assessment will include measures of quality, affordability, accessibility, availability and demand.

Study #: 40091
Title of Study: The Prevalence of Executive Cognitive Impairment and CLOX Screening Intervention: Focus on Racial and Ethnic Minority Health Care Disparities in the Hampton Roads Region in Virginia
Principal Investigator: Suk-hee Kim, Ph.D.
Date approved: June 30, 2008
Description of Study: This study will assess the research readiness of a Hampton Roads Region network of primary care clinics. A simple tool will be used to standardize elements of the clinical infrastructure to support research and provide clinic-level data regarding the extent of possible cognitive impairment among their patients.

Study #: 40092
Title of Study: Flight Attendants Health Study: The Incidence of Breast and Other Cancers Among Female Flight Attendants
Principal Investigator: Lynne Pinkerton, M.D., MPH
Date approved: July 14, 2008
Description of Study: This study will attempt to determine whether female flight attendants are at an increased risk of breast and other cancers and whether these risks are related to workplace exposures including cosmic radiation and circadian rhythm disruptions.

Study #: 40093
Title of Study: Baby Basics of Southwest Virginia
Principal Investigator: Merry McKenna
Date approved: September 23, 2008
Description of Study: This study will assess the efficacy of an intervention in southwest Virginia used to help empower pregnant women to access, act upon and understand health care information as a way to improve their pregnancy outcomes.

Study #: 40094
Title of Study: Virginia Youth Risk Behavior Survey (The Virginia Youth Survey Project)
Principal Investigator: Janice M. Hicks, Ph.D.
Date approved: October 17, 2008
Description of Study: This study will assess the health risk behaviors among youth and young adults, including behaviors that contribute to unintentional injuries and violence, tobacco use, alcohol and other drug use, and unhealthy dietary behaviors and physical activity.

Study #: 40095
Title of Study: National Study of Determinants of Early Diagnosis, Prevention and Treatment of TB
Date approved: October 27, 2008
Description of Study: This multi-state study will look at the timeliness of care-seeking, diagnosis, treatment and public health response in black and white TB patients in order to better understand the barriers to early intervention that may contribute to the disparity in the rates of TB between African-Americans and whites in the United States.

Study #: 40096
Title of Study: An Examination of Uninsured and Insured Cancer Patients in Virginia
Principal Investigator: Cathy J. Bradley, Ph.D.
Date approved: October 20, 2008
Description of Study: This study will examine differences in cancer diagnosis and treatment between uninsured and insured patients and assess whether there are treatment patterns and cost variations between safety net and non-safety net providers.

Study #: 40097
Title of Study: Mothers' Self-Video of Their Feeding Activities
Principal Investigator: Mary E. Thompson, MS, PNP-BC
Date approved: October 16, 2008
Description of Study: This study will explore the use of self-video documentation as a way to examine the feeding activities of low-income teen mothers and to gain a better understanding of parent feeding practices.

C. Exemption Reviews

Study #: 50051
Title of Study: Behavioral Risk Factor Surveillance System State-Added Questions 2008
Principal Investigator: Susan Kennedy Spain
Date approved: January 4, 2008
Description of Study: This study will assess the health status and risk behaviors of Virginia residents pertaining to firearms, oral health and social context.

Study #: 50052
Title of Study: Assuring Better Child Health and Development in Virginia
Principal Investigator: Joanne Boise
Date approved: January 4, 2008
Description of Study: This study will assess the effectiveness of a training being provided to four pilot sites in the use of a standardized pediatric developmental screening tool to assist primary care providers across Virginia make the transition to using this tool in their practices.

Study #: 50053
Title of Study: Interpregnancy Interval, Intervening Terminations and Birth Outcomes
Principal Investigator: Caroline C. Stampfel, MPH
Date approved: January 22, 2008
Description of Study: This study will be used to determine the prevalence of short interpregnancy intervals among Virginia residents. This study will also assess whether short interpregnancy intervals contribute to poor birth outcomes and if terminations of pregnancy between live births and short interpregnancy intervals contribute to poor birth outcomes.

Study #: 50054
Title of Study: Terrorism and Risk Perception Associated with the Color-Coded Homeland Security Advisory System: An Analysis of its Risk Message Among Public Health
Principal Investigator: Daniel Barnett, MD, MPH
Date approved: January 13, 2008
Description of Study: This study will assess the perceptions and responses of employees at public health agencies to changes in the National Color-Coded Homeland Security Advisory System and whether those perceptions and responses differ between urban and rural settings

Study #: 50055
Title of Study: Perinatal Depression Provider Survey
Principal Investigator: Joan Corder-Mabe, RNC, MS, WHNP
Date approved: February 21, 2008
Description of Study: This study is a post-intervention assessment of the attitudes, beliefs, knowledge and practices of health care providers in screening, diagnosing and treating perinatal depression in their patients. The intervention included a web-based educational curriculum, presentations and exhibits, and regional hospital round meetings.

Study #: 50056
Title of Study: Sudden Infant Death Syndrome (SIDS) Risk Reduction Survey
Principal Investigator: Joan Corder-Mabe, RNC, MS, WHNP
Date approved: February 22, 2008
Description of Study: This study is an assessment of Virginia health care facilities and their knowledge of, and compliance with current evidence-based safe sleep practices, recommendations and policies for infants in maternity and pediatric units.

Study #: 50057
Title of Study: A Descriptive Survey of Public Health Nursing Practice
Principal Investigator: Cynthia A. Goodrich, RN, MSN, EdD and Sharon J. Kopsis, RN, MSN, EdD
Date approved: April 8, 2008
Description of Study: This study assesses the practices and education of public health nurses in the Commonwealth of Virginia, with a focus on the nurses' perceptions of their preparation for their role in public health nursing.

Study #: 50058
Title of Study: Patterns of Firearm Injuries and Deaths in Virginia
Principal Investigator: P. Nicole Hendrix, Ph.D.
Date approved: May 14, 2008
Description of Study: This study will examine the distribution of gun injuries, deaths, crime and sales across Virginia, and will specifically explore whether there are relationships between firearm sales and firearm injuries, hospitalizations and crimes.

Study #: 50059
Title of Study: Pre-Term Labor Education Practices in Obstetrical Provider Offices in South Hampton Roads
Principal Investigator: Beth Kavinsky, RN, MNSc
Date approved: September 8, 2008
Description of Study: This study assesses the amount and type of education provided to expectant families by local obstetricians in the Hampton Roads area. Assessment results will be used to develop a focused educational program related to pre-term labor prevention.

Study #: 50060
Title of Study: Behavioral Risk Factor Surveillance System (BRFSS)
Principal Investigator: Susan Kennedy Spain
Date approved: October 6, 2008
Description of Study: This study will assess the health status and risk behaviors of Virginia residents pertaining to suicide, dental health and firearms.

Study #: 50061
Title of Study: Validation of Postmortem Infectious Disease Testing
Principal Investigator: Deborah Kay, MD
Date approved: November 25, 2008
Description of Study: This study will evaluate the sensitivity of donor screening assays used in testing for HIV, HBV and HCV.

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 2008		
Committee Members	Qualifications for Service	Institutional Affiliation
IRB CHAIR		
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
VOTING MEMBERS		
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	M.P.H. in Epidemiology & Program Officer	Williamsburg Community Health Foundation
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, of the VDH Office of Licensure and Certification	Virginia Department of Health
David H. Trump	M.D., M.P.H., FACPM and Director, Peninsula Health District	Peninsula Health District
ALTERNATE MEMBERS		
Edward L. Van Oeveren (inactive, on military leave beginning August 2006 and throughout all of calendar year 2008)	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

**Virginia Department of Health
Institutional Review Board**

**MINUTES
January 7, 2008
10:30 AM – 12:30 PM**

Members Present: Kathy Wibberly (Chair), Ana Colon, Carrie Dolan, Bethany Geldmaker, Gail Jennings,

Members Absent: Greg Stolcis, Ed Van Oeveren, Jessica Waugh

Guests: None

General Items/Announcements:

- ◆ The meeting convened at 10:38 AM. A quorum was present.
- ◆ Minutes from the October meeting were unanimously approved.
- ◆ Jessica Waugh will be moving from regular member to alternate member. We will need a replacement (non-scientific, external to VDH). Suggestions were made to invite a Minority Health Advisory Committee member and/or a Community Planning Group member. Please submit specific names you would recommend to Kathy.
- ◆ We are still waiting to hear back on Ed VanOeveren’s status. It was suggested that someone be appointed to fill his slot as an interim appointee, who can then also serve as an alternate when Ed returns. Suggested health district directors included Lillian Peake, Mark Levine and David Trump. Ana volunteered to see if David Trump would be interested.
- ◆ Kathy is still looking for feedback on the Collaborative Institutional Training Initiative (CITI) Web-based Training Program.
 - The following are basic learner instructions to logon to Virginia Department of Health Institutional Review Board (IRB) CITI site:
 - User should be instructed to go to www.citiprogram.org to register for CITI online training.
 - Once there, they simply click on “New Users Register Here”.
 - Next they should click on “The Protection of Human Research Subjects”
 - Under “Select your institution or organization” page they should select “Virginia Department of Health Institutional Review Board (IRB)” in the “Participating Institutions” drop down box.
 - Next they should proceed to create their own username and password and select the CITI Recommended Learner group; Biomedical Research Investigators, Social & Behavioral Research Investigators, **IRB Members**, Students conducting no more than minimal risk research or VDH General.
 - After going through registration process they should be ready and setup as CITI Learners under your Institution setup requirements.
- ◆ VDH IRB Meeting dates for 2008:

- Monday April 14, 2008
- Monday July 14, 2008
- Monday October 6, 2008

PRESENTATION OF NEW PROTOCOLS - EXEMPTION REVIEW:

Study #: 50050
Title of Study: Maternal Mortality Review Team
Principal Investigator: Victoria M. Kavanaugh, Ph.D.
Primary Reviewer: Bethany Geldmaker
Discussion: None.
Description of Action: Unanimously Approved

Study #: 50051
Title of Study: Behavioral Risk Factor Surveillance System State-Added Questions 2008
Principal Investigator: Susan Kennedy Spain
Primary Reviewer: Ana Colon
Discussion: None.
Description of Action: Unanimously Approved

Study #: 50052
Title of Study: Assuring Better Child Health and Development in Virginia
Principal Investigator: Joanne Boise
Primary Reviewer: Greg Stolcis
Discussion: None.
Description of Action: Unanimously Approved

PRESENTATION OF NEW PROTOCOLS - EXPEDITED REVIEW:

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
Primary Reviewer: Gail Jennings
Discussion:
Description of Action: Unanimously Approved.

PRESENTATION OF INITIAL SUBMISSIONS - FULL BOARD REVIEW:

None

CONTINUATION REVIEWS/RENEWALS:

Study #: 30003
Principal Investigator: Karen Day
Title of Protocol: “2007 Evaluation of a School Based Fluoride Rinse Program”
Discussion: None.
Description of Action: Unanimously Approved.

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: Unanimously Approved.

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

Study #: 40012
Principal Investigator: Kathleen F. Gaffney
Title of Protocol: "Smoking Relapse Among Mothers of Infants"
Discussion: There was interest by several members of the VDH IRB in the publication that resulted from this study. Copies will be made and disseminated.
Description of Action: Study completed and 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: None.
Description of Action: Unanimously Approved.

Study #: 40044
Principal Investigator: Allen N. Lewis, Ph.D.
Title of Protocol: "TPPI Richmond: Evaluation of the Reducing the Risk Program"
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"
Discussion: None.
Description of Action: Study completed and closed.

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"
Discussion: None.
Description of Action: Unanimously Approved.

Study #: 40071
Principal Investigator: Debra Perina, MD
Title of Protocol: "Trends in Motorcycle Crashes in Virginia "

Discussion: None.
Description of Action: Unanimously Approved.

Study #: 40072
Principal Investigator: Debra Perina, MD
Title of Protocol: “An Investigation of the Impact of Guardrail Type and Vehicle Classification on Crash Severity”

Discussion: None.
Description of Action: Unanimously Approved.

OTHER (MINOR MODIFICATIONS, ETC):

Study #: 30003
Principal Investigator: Karen Day
Title of Protocol: “2007 Evaluation of a School Based Fluoride Rinse Program”
Type of Review: Minor Modification Request
Description: Parent questionnaire will delete question pertaining to number of years that child has been enrolled in the fluoride rinse program due to issues with recall.

Discussion: None.
Description of Action: Unanimously Approved.

Study #: 40068
Principal Investigator: Dena Bensen, MPH
Title of Protocol: “Medical Monitoring Project 2006”
Type of Review: Minor Modification Request
Description: A number of wording changes being requested for data abstraction forms.

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”

Type of Review: Minor Modification Request
Description: Expand the study to include 2007 cases/controls and identification of controls ages <5 years through community phone book.

Discussion: None.
Description of Action: Unanimously Approved.

Meeting was adjourned at 12:21 PM.

**Virginia Department of Health
Institutional Review Board**

**MINUTES
April 14, 2008
10:30 AM – 12:30 PM**

Members Present: Kathy Wibberly (Chair), Ana Colon, Carrie Dolan, Bethany Geldmaker, Gail Jennings, David Trump

Members Absent: Greg Stolcis, Ed Van Oeveren, Jessica Waugh

Guests: None

General Items/Announcements:

- ◆ The meeting convened at 10:37 AM. A quorum was present. New member, David Trump was introduced. Change in status of Carrie Dolan from internal to external member was noted. One vacant seat presently remains for a “non-scientific” member (either internal or external). Recommendations are requested.
- ◆ The process for amending the “Regulations for the Conduct of Human Research” in the Virginia Administrative Code is underway to make them consistent with changes made to the Code of Virginia and with federal regulatory changes made in recent years. A new VDH IRB Standard Operating Procedures and Guidelines for Obtaining Review document will be prepared and disseminated once these changes are approved.
- ◆ Minutes from the January meeting were unanimously approved.
- ◆ Continuing education opportunities and materials were reviewed. These include:
 - 2008 Virginia IRB Consortium
 - Distribution of article by Carrie Dolan entitled “Principal Investigator Views of the IRB System”
 - Brief discussion about PowerPoint disseminated about GIS and Privacy and Confidentiality
- ◆ VDH IRB Meeting dates for 2008:
 - Monday July 14, 2008
 - Monday October 6, 2008

PRESENTATION OF NEW PROTOCOLS - EXEMPTION REVIEW:

Study #:	50053
Title of Study:	Interpregnancy Interval, Intervening Terminations and Birth Outcomes
Principal Investigator:	Caroline C. Stampfel, MPH
Primary Reviewer:	Bethany Geldmaker
Discussion:	None.
Description of Action:	Unanimously Approved

Study #: 50054
Title of Study: Terrorism and Risk Perception Associated with the Color-Coded Homeland Security Advisory System: An Analysis of its Risk Message Among Public Health
Principal Investigator: Daniel Barnett, MD, MPH
Primary Reviewer: Greg Stolcis
Discussion: None.
Description of Action: Unanimously Approved

Study #: 50055
Title of Study: Perinatal Depression Provider Survey
Principal Investigator: Joan Corder-Mabe, RNC, MS, WHNP
Primary Reviewer: Gail Jennings
Discussion: None.
Description of Action: Unanimously Approved

Study #: 50056
Title of Study: Sudden Infant Death Syndrome (SIDS) Risk Reduction Survey
Principal Investigator: Joan Corder-Mabe, RNC, MS, WHNP
Primary Reviewer: Greg Stolcis
Discussion: None.
Description of Action: Unanimously Approved

Study #: 50057
Title of Study: A Descriptive Survey of Public Health Nursing Practice
Principal Investigator: Cynthia A. Goodrich, RN, MSN, EdD and Sharon J. Kopsis, RN, MSN, EdD
Primary Reviewer: Bethany Geldmaker
Discussion: The need for gatekeepers for VDH employee studies and adaptations of instruments needed to reflect and understand of the state infrastructure.
Description of Action: Unanimously Approved

PRESENTATION OF NEW PROTOCOLS - EXPEDITED REVIEW:

Study #: 40085
Title of Study: Nursing Home Oral Health Intervention
Principal Investigator: Karen C. Day
Primary Reviewer: Carrie Dolan
Discussion: Well written protocol, could be stripped of identifiers and used as a sample for others.
Description of Action: Unanimously Approved.

Study #: 40086
Title of Study: Oral Health Assessment of Virginia Elders
Principal Investigator: Karen C. Day

Primary Reviewer: Ana Colon
Discussion: None
Description of Action: Unanimously Approved.

Study #: 40087
Title of Study: Richmond Region WIC Oral Health Intervention
Principal Investigator: Karen C. Day
Primary Reviewer: Bethany Geldmaker
Discussion: None
Description of Action: Unanimously Approved.

Study #: 40088
Title of Study: Prehospital Patient Triage in Mass Casualty Incidents: An Engineering Management Analysis and Strategy
Principal Investigator: John Harrald, Ph.D.
Primary Reviewer: Gail Jennings
Discussion: None
Description of Action: Unanimously Approved.

PRESENTATION OF INITIAL SUBMISSIONS - FULL BOARD REVIEW:

None

CONTINUATION REVIEWS/RENEWALS:

Study #: 40008
Principal Investigator: Sue Cantrell
Title of Protocol: "Rural Appalachia Cancer Demonstration Project – Objective 2"
Discussion: None.
Description of Action: Study completed.

Study #: 40032
Principal Investigator: Frederick Angulo, DVM, PhD
Title of Protocol: "Interviews of Persons From Which Enteric Bacterial Isolates Have Been Cultured with Uncommon Antimicrobial Resistance Patterns"
Discussion: None.
Description of Action: Unanimously approved.

Study #: 40055
Principal Investigator: Kathryn Laughon
Title of Protocol: "Rural Women's Health Study"
Discussion: None.
Description of Action: Study completed.

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"

Discussion: None.
Description of Action: Unanimously approved.

Study #: 40061
Principal Investigator: Katrina Armstrong, MD, MSCE
Title of Protocol: "Segregation and Racial Disparities in Prostate Cancer"
Discussion: None.
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"
Discussion: None.
Description of Action: Study completed.

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"
Discussion: None.
Description of Action: Study completed.

Study #: 40075
Principal Investigator: Lynne Penberthy, MD, MPH
Title of Protocol: "Improving Capture of Chemotherapy Information using Physician Office Billing"
Discussion: None.
Description of Action: Unanimously approved.

Study #: 40076
Principal Investigator: Lynn Rosenberg, Sc.D.
Title of Protocol: "Black Women's Health Study: A Follow-up Study"
Discussion: None.
Description of Action: Unanimously approved.

Study #: 40077
Principal Investigator: John M. Quillin
Title of Protocol: "Matching of Mid-Atlantic Twin Registry (MATR) and Virginia Cancer Registry (VCR)"
Discussion: None.
Description of Action: Unanimously Approved.

OTHER (MINOR MODIFICATIONS, ETC):

Study #: 40022
Principal Investigator: Allen Lewis
Title of Protocol: "Alexandria: Evaluation of Pro-Teen/Pro-Youth and Project Step Out Programs"
Type of Review: Minor Modification Request
Description: Form A: added 4 questions (two are from the PMEDS and one is

from "Focus on Kids" eval. tool, one I made up): question 12,13,24 & 26
Form B: added 3 questions (pretty much same as with form A):
questions 17,19 and 27
Changes to informed consent form to comply with TA manual
recommendations for all TPPI programs

Discussion: None.
Description of Action: Unanimously approved.

Study #: 40079
Principal Investigator: Karen Day
Title of Protocol: "2007 Piedmont Health District Pilot Study"
Type of Review: Minor Modification Request
Description: Expansion of study to include third graders from Crater Health District in addition to the Piedmont Health District originally proposed. Screenings and survey questions will only involve dental related items. Height/weight measurements and BMI/Nutrition/Physical Activity questions will be removed from the parent survey.
Discussion: None.
Description of Action: Unanimously Approved.

Meeting was adjourned at 12:31 PM.

**Virginia Department of Health
Institutional Review Board**

**MINUTES
July 14, 2008
10:30 AM – 12:30 PM**

Members Present: Kathy Wibberly (Chair), Ana Colon, Carrie Dolan, Bethany Geldmaker, Gail Jennings, Greg Stolcis, David Trump

Members Absent: Ed Van Oeveren, Jessica Waugh

Guests: None

General Items/Announcements:

- ◆ The meeting convened at 10:38 AM. A quorum was present.
- ◆ Minutes from the April meeting were unanimously approved.
- ◆ Continuing education
 - opportunities to obtain videoconference trainings are being investigated
- ◆ VDH IRB Meeting dates for 2008:
 - Monday October 6, 2008

PRESENTATION OF NEW PROTOCOLS - FULL BOARD REVIEW:

None

PRESENTATION OF NEW PROTOCOLS - EXPEDITED REVIEW:

Study #:	30006/40092
Title of Study:	Flight Attendants Health Study: The Incidence of Breast and Other Cancers
	Among Female Flight Attendants
Principal Investigator:	Lynne Pinkerton, M.D., MPH
Discussion:	The P.I., Lynne Pinkerton, provided a brief overview of the study via conference call. Although the proposal was submitted for full board review, it was agreed upon that it met the criteria for expedited review.
Description of Action:	Unanimously Approved
Study #:	40089
Title of Study:	Hampton Roads VDH/VIMS Clam Project
Principal Investigator:	Howard Kator, Ph.D.
Primary Reviewer:	Ana Colon
Discussion:	None.
Description of Action:	Unanimously Approved
Study #:	40090
Title of Study:	Barriers to Behavioral Health Care in Rural Virginia

Principal Investigator: Wendy Kliewer, Ph.D.
Primary Reviewer: Greg Stolcis
Discussion: Results and findings should be shared with DMHMRSAS and with the mental Health Reform Commission.
Description of Action: Unanimously Approved

Study #: 40091
Title of Study: The Prevalence of Executive Cognitive Impairment and CLOX Screening
 Intervention: Focus on Racial and Ethnic Minority Health Care Disparities
 in the Hampton Roads Region in Virginia

Principal Investigator: Suk-hee Kim, Ph.D.
Primary Reviewer: Carrie Dolan
Discussion: None.
Description of Action: Unanimously Approved

PRESENTATION OF NEW PROTOCOLS - EXEMPTION REVIEW:

Study #: 50058
Title of Study: Patterns of Firearm Injuries and Deaths in Virginia
Principal Investigator: P. Nicole Hendrix, Ph.D.
Primary Reviewer: David Trump
Discussion: Reviewers were interested in how jurisdiction/location of injuries and deaths were determined and/or assigned..
Description of Action: Unanimously Approved

CONTINUATION REVIEWS/RENEWALS:

Study #: 30005
Principal Investigator: Karen Day, DDS, MS, MPH
Title of Protocol: "Fluoride Varnish Study"
Discussion: Study summary presented.
Description of Action: Study completed.

Study #: 40016
Principal Investigator: Melvin Wilson
Title of Protocol: "Early Family Centered Prevention of Conduct Disorder and Drug Use Risk in Rural Populations"
Discussion: None.
Description of Action: Unanimously Approved.

Study #: 40019
Principal Investigator: Elizabeth Eustis-Turf, Ph.D.
Title of Protocol: "TPPI: Portsmouth: Becoming a Responsible Teen (BART) Project Outcome Evaluation Study"
Discussion: None.
Description of Action: Study completed, awaiting study summary report.

Study #: 40021
Principal Investigator: Elizabeth Eustis-Turf, Ph.D.
Title of Protocol: "TPPI: Eastern Shore Teen Pregnancy Prevention Program"
Discussion: None.
Description of Action: Study completed, awaiting study summary report.

Study #: 40027
Principal Investigator: Fern R. Hauck, M.D., M.S.
Title of Protocol: "Cross Cultural Infant Care Practices in Virginia"
Discussion: None.
Description of Action: Unanimously Approved.

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 J. Stampfer, MD, DrPH
Title of Protocol: "Cohort Cancer Registry Follow-up Study"
Discussion: None.
Description of Action: Unanimously Approved.

Study #: 40047
Principal Investigator: Tejpratap Tiwari
Title of Protocol: "Risk Factors for Mortality Due to Pertussis Among Infants in the U.S. – A Case Control Study"
Discussion: Study summary presented.
Description of Action: Study completed.

Study #: 40050
Principal Investigator: Nancy Ford, MPH, RN
Title of Protocol: "Folic Acid Supplement Distribution Program"
Discussion: Study summary presented.
Description of Action: Study completed.

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

Study #: 40058
Principal Investigator: James Patterson, M.D.
Title of Protocol: "Desmoplastic Melanoma: A Clinicopathologic Study"
Discussion: Study summary presented.
Description of Action: Study completed.

Study #: 40060
Principal Investigator: Dr. Karen C. Day
Title of Protocol: "1999 Virginia Statewide Oral Health Needs Assessment"
Discussion: Study summary presented.
Description of Action: Study completed.

(VDH IRB Members Took A Brief Break to Get Their Lunches)

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"
Discussion: None.
Description of Action: Unanimously Approved.

Study #: 40065
Principal Investigator: Elizabeth Eustis-Turf, Ph.D.
Title of Protocol: "Evaluation of the STOP-DAT Teenage Pregnancy Prevention Program"
Discussion: None.
Description of Action: Study completed, awaiting study summary report.

Study #: 40081
Principal Investigator: Susan Modesitt, MD
Title of Protocol: "Cancer Prevalence in Obese Women Who Underwent Bariatric Surgery"
Discussion: None.
Description of Action: Unanimously Approved.

Study #: 40082
Principal Investigator: Marilee Comfort, Ph.D., MPH
Title of Protocol: "Online Training for a New Parent-Child Assessment Tool"
Discussion: Study summary presented.
Description of Action: Study completed.

OTHER (MINOR MODIFICATIONS, ETC):

Study #: 40016
Principal Investigator: Melvin Wilson
Title of Protocol: "Early Family Centered Prevention of Conduct Disorder and Drug Use Risk in Rural Populations"
Type of Review: Minor Modification
Description: Wording changes in informed consent form to reflect 2nd phase of the study.
Discussion: None.
Description of Action: Unanimously Approved.

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”
Type of Review:	Noncompliance
Description:	<p>Study suspended and reported to ORHP due to noncompliance</p> <ul style="list-style-type: none"> ♦ This study was reviewed and approved on 11/26/2004. ♦ Continuation review materials were submitted on 10/31/2005 and continuation was approved through 11/26/2006. ♦ Reminder email and continuation review forms were sent to the P.I. on 10/13/2006 with no response. ♦ Another email indicating that the continuation review form was due and not received yet and requesting a response ASAP was sent on 11/29/2006 with no response. ♦ Follow up email by VDH collaborator on December 1, 2006 to the P.I. received a response and continuing review forms were finally submitted on 12/01/2006 (five days late). Continuation was approved through 11/26/2007. ♦ Reminder email and continuation review forms were sent to the P.I. on 10/2/2007 with no response. ♦ 30 day overdue notification email was sent on January 4, 2008 citing that they were not out of compliance and giving the PI 5 days to comply or have the study suspended by the VDH IRB and reported to ORHP. No response. ♦ Email sent April 4, 2008 notifying the PI of suspension of the study by the VDH IRB and reporting to OHRP. ♦ Continuation review form indicating case has been closed received after notification of suspension.
Discussion:	None.
Description of Action:	Unanimously Approved.
Study #:	40052
Principal Investigator:	William J. Blot, Ph.D.
Title of Protocol:	"Follow-Up Study for Cancer Incidence for the Southern Community Cohort Study"
Type of Review:	Minor Modification
Description:	Study has entered into a 2 nd grant period. Updated study plan has been included to reflect the new dates/timeline. Updates do not include any significant changes in the protocol.
Discussion:	None.
Description of Action:	Unanimously Approved.

Meeting was adjourned at 12:12 PM.

**Virginia Department of Health
Institutional Review Board**

**MINUTES
October 6, 2008
10:30 AM – 12:30 PM**

Members Present: Kathy Wibberly (Chair), Ana Colon, Carrie Dolan, Bethany Geldmaker, Gail Jennings, , David Trump

Members Absent: Greg Stolcis, Ed Van Oeveren

Guests: None

General Items/Announcements:

- ◆ The meeting convened at 10:47 AM. A quorum was present.
- ◆ Minutes from the July meeting were unanimously approved.
- ◆ Continuing education
 - Members are encouraged to explore and take advantage of the CITI training/continuing education that is available to us right now. With budget issues, it is unclear how long we will be able to maintain our subscription.
 - It was recommended that we also explore some joint training/continuing education efforts with our different academic partners with IRBs.
- ◆ VDH IRB Meeting dates for 2009:
 - TBD via email

PRESENTATION OF NEW PROTOCOLS – EXEMPTION REVIEW:

Study #: 50059
Title of Study: Pre-Term Labor Education Practices in Obstetrical Provider Offices in South Hampton Roads
Principal Investigator: Beth Kavinsky, RN, MNSc
Primary Reviewer: Carrie Dolan
Discussion: None
Description of Action: Unanimously Approved

Study #: 50060
Title of Study: Behavioral Risk Factor Surveillance System (BRFSS)
Principal Investigator: Susan Kennedy Spain
Primary Reviewer: Ana Colon
Discussion: Limitations of sampling and applicability of finding to localities was discussed. It was felt that localities should be given the option to pay for their own oversampling if desired.
Description of Action: Unanimously Approved

PRESENTATION OF NEW PROTOCOLS - EXPEDITED REVIEW:

Study #: 40089
Title of Study: Hampton Roads VDH/VIMS Clam Project
Principal Investigator: Howard Kator, Ph.D.
Primary Reviewer: Ana Colon
Discussion: None.
Description of Action: Unanimously Approved.

Study #: 40093
Title of Study: Baby Basics of Southwest Virginia
Principal Investigator: Merry McKenna
Primary Reviewer: Bethany Geldmaker
Discussion: Study is very basic and could have been more rigorous. The research and eval committee could/should have provided some assistance in this regard.
Description of Action: Unanimously Approved

Study #: 40094
Title of Study: Virginia Youth Risk Behavior Survey (The Virginia Youth Survey Project)
Principal Investigator: Janice M. Hicks, Ph.D.
Primary Reviewer: Gail Jennings
Discussion: None.
Description of Action: Approvable upon receipt of final survey and response to several clarifying questions.

PRESENTATION OF NEW PROTOCOLS - FULL BOARD REVIEW:

None.

CONTINUATION REVIEWS/RENEWALS:

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

Study #: 40021
Principal Investigator: Elizabeth Eustis-Turf, Ph.D.
Title of Protocol: "TPPI: Eastern Shore Teen Pregnancy Prevention Program"
Discussion: Study summary presented.
Description of Action: Study completed.

Study #: 40022
Principal Investigator: Elizabeth Eustis-Turf, Ph.D.
Title of Protocol: "Alexandria: Evaluation of Pro-Teen/Pro Youth and Project Step Out Programs"

Discussion: Study summary presented.
Description of Action: Study completed.

Study #: 40044
Principal Investigator: Elizabeth Eustis-Turf, Ph.D.
Title of Protocol: "TPPI Richmond: Evaluation of the Reducing the Risk Program"
Discussion: Study summary presented.
Description of Action: Study completed.

Study #: 40056
Principal Investigator: Elizabeth Eustis-Turf, Ph.D.
Title of Protocol: "Evaluation of the Postponing Sexual Involvement Program"
Discussion: Study summary presented.
Description of Action: Study completed.

Study #: 40068
Principal Investigator: Dena Bensen
Title of Protocol: "Medical Monitoring Project 2006"
Discussion: See minor modification request
Description of Action: Unanimously approved.

Study #: 40083
Principal Investigator: John Dreyzehner, MD, MPH, FACOEM
Eleanor S. Cantrell, MD
Title of Protocol: "Flu Clues: A Childhood Influenza Vaccination Project"
Discussion: See minor modification request
Description of Action: Unanimously approved.

Study #: 40084
Principal Investigator: Deborah M. Harris
Title of Protocol: "Integration of HIV/AIDS Testing and Prevention Services in Three Local Title X Family Planning Projects"
Discussion: None
Description of Action: Unanimously approved.

OTHER (MINOR MODIFICATIONS, ETC):

Study #: 40068
Principal Investigator: Dena Bensen
Title of Protocol: "Medical Monitoring Project 2006"
Type of Review: Minor Modification
Description: Added medical care definition clarification, changed population to include psychiatric all sampled patients (deleted instructions to exclude outpatient facilities), added definition of EPL (estimated patient load), added more detail on recruitment strategies, deleted section on inpatient evaluations, added guidance on appropriate interpreters and guidelines for translated

interviews, added description of workbooks and naming conventions, added facility attributes description, added that sites should develop adverse events protocols and need to notify CDC of any adverse events within specific time frames.

Discussion: None.
Description of Action: Unanimously Approved.

Study #: 40083
Principal Investigator: John Dreyzehner, MD, MPH, FACOEM
Eleanor S. Cantrell, MD
Title of Protocol: "Flu Clues: A Childhood Influenza Vaccination Project"
Type of Review: Minor Modification
Description: Addition of Eleanor S. Cantrell, MD as co-investigator and expansion of project to include all school systems within the two health districts (primary/elementary and middle schools).
Discussion: None.
Description of Action: Unanimously Approved.

Meeting was adjourned at 12:14 PM.