REPORT TO THE COMMISSIONER:

ACTIVITIES OF THE VIRGINIA DEPARTMENT OF HEALTH INSTITUTIONAL REVIEW BOARD FOR CALENDAR YEAR 2011

Submitted by

Diane Helentjaris, MD, MPH
Chair, VDH IRB

REPORT TO THE COMMISSIONER:
VIRGINIA DEPARTMENT OF HEALTH (VDH)
INSTITUTIONAL REVIEW BOARD (IRB)
FOR CALENDAR YEAR 2011

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 VDH, a description of the proposed human research project shall be submitted to a research review committee for review and approval. VDH subsequently appointed an IRB. In addition, a policy document, *The Institutional Review Board (IRB) of the Virginia Department of Health (VDH): Guidelines and Procedures for Obtaining Review,* was developed and approved by the Commissioner in January 2001, updated in March 2005 and then again in December 2010.

The Office for Human Research Protections (OHRP), within the U.S. Department of Health and Human Services (DHHS), is responsible for ensuring the safety and welfare of people who participate in HHS-sponsored research. VDH has voluntarily registered and has applied for and received Federalwide Assurance for its IRB from OHRP. Registration with OHRP facilitates DHHS's effort to establish effective communication with IRBs. In addition, receiving an assurance from OHRP formalizes an institution's commitment to protect human subjects.

Depending on the level of risk of the research protocol and the participant population, IRBs may conduct either an exemption review, expedited review or full board review.

Under Federal regulations [45 CFR 46.101 (b)], certain categories of research that present little or no risk to human subjects (non-vulnerable subjects) do not require ongoing monitoring and review by an IRB. However, IRB staff, in consultation with an IRB chair, must make the determination that the study does indeed meet the criteria for exemption before the research study may commence. This type of review is called "exemption review". If the risks to human subjects appear questionable or the project does not fit into the federally defined categories for exemption, the IRB will notify the investigator that he/she must submit the study as a new protocol for either full or expedited review. If a study falls into one of the exempt categories, researchers still have ethical responsibilities to protect participants' rights.

Under Federal regulations [45 CFR 46.101 (b)], certain categories of research involving no more than minimal risk as well as minor changes to approved research, qualify for what is called "expedited review". In these instances, the IRB Chair or a designated voting member or group of voting members review the proposed research rather than the entire IRB.

When full board review is necessary, the research proposal is presented and discussed at a meeting at which a quorum of IRB members is present. For the research to be approved, it must receive the approval of a majority of those voting members present. This is considered "full board review".

In 2011, the Commissioner appointed Dr. Diane Helentjaris, Director of the Office of Family Health Services, as the chair of the VDH IRB following the resignation of Kathy Wibberly.

The following is a summary of the activities and actions of the VDH IRB as per state "Regulations for the Conduct of Human Research" (12 VAC 5-20-50) during calendar year 2011.

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

A. Full Board Reviews

None.

B. Expedited Reviews:

Study #: 40126
Title of Study: WIC Program Assessment
Principal Investigator: Mary Beth Dunkenberger
Date approved: February 17, 2011
Description of Study: This study is a non-experimental program evaluation designed to assess the use and barriers of the WIC program for the population of foster care parents. The tools for evaluation are a survey and focus groups. The subject pool is foster care parents who are either state-certified agency providers or private providers in Virginia. The total subject pool will be approximately 2000 foster care parents.

Study #: 40127
Title of Study: Evaluation of the text4baby Mobile Pre-natal Health Program
Principal Investigator: W. Douglas Evans, PhD
Date approved: February 10, 2011
Description of Study: This is a pilot study of audience reaction and utilization of prenatal and post-partum care promotion text messages delivered by the text4baby (T4B) mobile health program. The program is designed for low-income women who are pregnant or have recently given birth. This sample will consist only of women who initially seek pre-natal care from the Fairfax Health Department and then participate in the InovaCares clinic.

Study #: 40128
Title of Study: Guided Imagery Effects on Pregnancy Symptoms and Outcomes
Principal Investigator: Nancy Jallo, PhD, RNC,FNP-BC,CNS
Date approved: March 10, 2011
Description of Study: This study will provide baseline data for further research to test the biobehavioral efficacy of the intervention – guided imagery effects on pregnancy symptoms and outcomes- in larger samples with multiple races/ethnicities as well as test the model during the postpartum period for maternal well-being and infant development.

Study #: 40129
Title of Study: Analysis of Animal Exposure in South East Virginia
Principal Investigator: Hind Baydoun
Date approved: February 24, 2011
Description of Study: This study will create a database that will be used to recognize patterns and associations between geographic and demographic factors that may increase the risk of an animal exposure. To achieve this recorded animal exposure data will be collected and sited on a map using GIS software and will be analyzed looking for patterns and trends.

Study #: 40130
Title of Study: Program for Child to Adult Transition of Sickle Cell Care
Principal Investigator: Wally Smith, MD
Date approved: April 18, 2011
Description of Study: This study will assist with research in evaluating areas of deficit as adolescent sickle cell patients prepare to enter adult care, allowing education and intervention in areas where the patient lacks insight. The transition/questionnaires will be administered by designated staff at each clinic to patients ages 15-21 who are currently participating in a sickle cell transition program.

Study #: 40131
Title of Study: Project Connect: Evaluation of a Public Health Partnership to Prevent Violence Against Women
Principal Investigator: Elizabeth Miller, MD, PhD
Date approved: April 14, 2011
Description of Study: This study will evaluate a large multi-state initiative of the Family Violence Prevention Fund (a national clearinghouse for violence prevention and intervention) funded by the Office of Women's Health. Each of the 8 states (Michigan, Iowa, Maine, Texas, Georgia, Ohio, Virginia and Arizona) and 2 Tribal Organization (Hoopa and Southern Indian Tribes) involved in Project Connect receive funding to create a leadership team that will bridge public health programs promoting women health with domestic violence and sexual assault prevention.

Study #: 40132
Title of Study: Smoking Cessation During Pregnancy
Principal Investigator: Linda Bullock, PhD, RN, FAAN
Date approved: April 18, 2011
Description of Study: This pilot study is a quasi-experimental design to test the feasibility of delivering a smoking cessation intervention in the form of nicotine patches; specific smoking cessation educational material and weekly telephone support calls to 10 low-income couples who are expecting a baby and both members of the dyad continue to smoke during pregnancy. The information obtained from this study will be used to demonstrate the efficacy of the intervention in Virginia for a proposed randomized controlled trial.

Study #: 40133
Title of Study: What Do Parents Think About the Best Ways to Prevent Illnesses in their Children and About Vaccinations?
Principal Investigator: Eleanor S. Cantrell, MD & John Dreyzehner, MD, MPH
Date approved: May 31, 2011
Description of Study: This study will use multi-mode data collection with a flu survey and focus groups for parents/legal guardians in Wise, Lee Scott, Dickerson, Russell, Tazewell, and Buchanan Counties and the City of Norton to gain insight into what parents think are the best ways to prevent illness in children and about vaccinations. These were areas where targets were not met for the H1N1 vaccination. Participants will be recruited by school nurses and identified as either parents that vaccinated or parents that did not have children vaccinated.

Study #: 40134
Title of Study: Linkage to Virginia Cancer Registry for Ongoing Retrospective Study of Satellite Workers
Principal Investigator: Joseph K. McLaughlin, PhD
Date approved: June 6, 2011
Description of Study: This is a retrospective study of employees who worked at the Valley Forge Facility that have been diagnosed with renal cell cancer. The purposed data linkage with the Virginia Cancer Registry is to determine whether cancer incidence in the cohort of Valley Forge aerospace workers is elevated compared with the general population, and to quantify the extent of an increased incidence rates of any particular type of cancer.

Study #: 40135
Title of Study: Impact of Workplace Colorectal Cancer Screening Program
Principal Investigator: Resa M. Jones, MPH, PhD
Date approved: July 26, 2011
Description of Study: This is a cross-sectional study, designed to assess the impact of a workplace educational program regarding colorectal cancer screening and prevention. A 4-page self administered questionnaire that includes items on knowledge, intentions, beliefs, screening history, demographic information, information regarding the Colon Cancer Free Zone workshop and thoughts on the program will be administered.

Study #: 40136
Title of Study: Social-Spatial Risk and Protective Mechanisms in Urban Adolescent Substance Use
Principal Investigator: Michael J. Mason, PhD
Date approved: September 26, 2011
Description of Study: This study will model the evolution of risk and protective mechanisms affecting substance use for urban youth. This model constitutes a necessary step for building scientifically driven preventive interventions.

Study #: 40137

Title of Study: The Association Between Maternal Obesity and Adequacy of Prenatal Care
Principal Investigator: Saba Masho, MD, MPH
Date approved: October 19, 2011
Description of Study: This study will examine the influence of pre-pregnancy BMI on adequacy of prenatal care using de-identified, linked Virginia Pregnancy Risk Assessment Monitoring System (PRAMS) and birth certificate data. These findings can possibly aid health care providers to target populations who are at increased risk for inadequate prenatal care, and perhaps ultimately lead to fewer poor birth outcomes that are often associated with less than optimal prenatal care.

Study #: 40138
Title of Study: Children's Understanding of Arrows
Principal Investigator: Krisztina Jakobsen, PhD
Date approved: October 19, 2011
Description of Study: This study will examine three and four year old children randomly assigned to one of four computer based tasks to determine children's ability to use arrows to direct their attention.

Study #: 40139
Title of Study: Garrett Lee Smith Youth Suicide Prevention Program Evaluation
Principal Investigator: Stephanie Goodman, MPH
Date approved: October 20, 2011
Description of Study: This is an evaluation of the Garrett Lee Smith Youth Suicide Prevention Program. The study will assist communities to improve suicide prevention effectiveness and assist decision makers at SAMHSA to direct federal resources to effective programs.

Study #: 40140
Title of Study: Lord Fairfax Health Department Youth Risk Behavior Survey
Principal Investigator: Charles Devine, MD
Date approved: October 18, 2011
Description of Study: This study survey will monitor six categories of priority health risk behaviors among youth and young adults, including behaviors that contribute to unintentional injuries and violence; tobacco use; alcohol and other drug use; sexual behaviors that contribute to unintended pregnancies and sexually transmitted infections (STIs); unhealthy dietary behaviors; physical inactivity and monitor the prevalence of obesity and asthma.

Study #: 40141
Title of Study: Response Program Evaluation
Principal Investigator: Stephanie Goodman, MPH
Date approved: October 20, 2011

Description of Study: This is an evaluation of the RESPONSE Program to be implemented in schools by request. Following implementation of the program students and staff will be surveyed and results will be used primarily for internal program evaluation purposes. Data may be used as program justification to funders or to promote the RESONSE programs to schools, stakeholders or other interested parties.

Study #: 40142
Title of Study: Predictors of Communication and Family Planning Decision Making Among Latino Couples
Principal Investigator: Jacqueline M McGrath, PhD, RN, FNAP, FAAN
Date approved: November 1, 2011
Description of Study: This study will test a model that predicts communication and decision making in regards to family planning and contraceptive use among Latino couples. The goal is to avoid unintended pregnancy and associated negative consequences (e.g., low birth weight, child development problems). Both partners need to agree to participate in the study.

Study #: 40143
Title of Study: Knowledge of HPV in Relationship to Acceptance and Barriers of HPV Vaccination
Principal Investigator: Jessica Sharp, PhD, FNP-BC, CRNA
Date approved: November 28, 2011
Description of Study: This study will explore whether there is a relationship between an educational program and acceptance of HPV vaccine.

Study #: 40144
Title of Study: Project Connect: Evaluation of a Public Health Partnership to Prevent Violence Against Women
Principal Investigator: Elizabeth Miller, MD, PhD
Date approved: December 30, 2011
Description of Study: This study is a large multi-state evaluation of an intimate partner violence sexual assault training program for public health professionals engaged in adolescent health, reproductive health and maternal health programs (specifically home visitation programs).

C. Exemption Reviews

Study #: 50091
Title of Study: The Effectiveness of Point of Care Lead Testing in WIC Clinic with Portable Analyzers in Improving Blood Lead Screening Rates and Follow-up Time Among Children at Risk for Lead Poisoning
Principal Investigator: Margie Walling, Mary Jean Brown, ScD, RN and Chinaro Kennedy, Dr. PH, MPH
Date approved: January 4, 2011

Description of Study: This study will analyze existing data from two separate VDH data bases: WIC-NET and LeadTrax. The purpose of the study is to correlate lead screening rates with visits to the City of Richmond's WIC Clinics (WIC-Net) during three different time periods. The purpose of the study is to determine the effectiveness of point of care lead testing in the WIC clinic in improving blood lead screening rates and follow-up.

Study #: 50092
Title of Study: Assessment of Educational, Clinical and Advocacy Needs Related to Cancer in Southside and Southwest Counties of Virginia
Principal Investigator: Gordon Dean Ginder, MD
Date approved: January 28, 2011
Description of Study: This study is a comprehensive cancer needs assessment to characterize the burden of cancer in four health districts within Southside and Southwest Virginia: Crater, Mount Rogers, Piedmont and Pittsylvania/Danville.

Study #: 50093
Title of Study: Behavioral Risk Factor Surveillance System (BRFSS)
Principal Investigator: Susan Kennedy Spain
Date approved: December 22, 2010
Description of Study: This study is a part of a cooperative agreement with the Centers for Disease Control and will include optional and state added questions that assess the health status and risk behaviors of Virginia residents pertaining to preconception health/family planning, pre-diabetes, actions to control high blood pressure, random child selection module, child immunization, heart attack and stroke, prescription drug abuse and disability.

Study #: 50095
Title of Study: Educating Future Health Providers to Serve Rural Populations
Principal Investigator: Janet L. McDaniel, PhD
Date approved: January10, 2011
Description of Study: This study involves a survey of academic programs about how they educate future healthcare providers to work in rural areas and specifically how they are training their students to practice within patient-centered medical home models and integrate behavioral health with primary care.

Study #: 50096
Title of Study: Foodscapes, Inequality and Disease: Interrelationships between Food Environment and Public Health in Charlottesville, VA
Principal Investigator: Rebecca M. Tippett, PhD
Date approved: February 25, 2011

Description of Study: This study will use existing death records data from the Virginia Department of Health to construct aggregate mortality statistics for selected geographies within the Charlottesville Metropolitan Statistical Area.

Study #: 50097
Title of Study: Chronic Disease Burden Report for Virginia Department of Health
Principal Investigator: Henry J. Carretta
Date approved: February 17, 2011
Description of Study: This study will analyze data from the 2004-2008 VHI hospital discharge database, the 2004-2008 Virginia mortality statistics, the 2007-2008 core Behavioral Risk Factor Surveillance Survey and the 2002-2006 Virginia Cancer Registry. The aim of these activities is to reproduce a data book similar in content to those produced by VDH staff in the past.

Study #: 50098
Title of Study: Physicians Survey of Beliefs and Practices Pertaining to Sports Related Concussions
Principal Investigator: Witemba Kabange
Date approved: March 10, 2011
Description of Study: This study will survey health care providers (physicians) in Virginia regarding sports-related concussions in student athletes regarding guidelines for the assessment, diagnosis and management of concussion and decision-making regarding return to play post-concussion; concerns and liability and malpractice involving implementation of the law and input concerning how VDH can assist physicians on implementing the new law.

Study #: 50099
Title of Study: Human Papillomavirus Vaccination: Barriers to Vaccination Among Young Adult Women
Principal Investigator: Madeleine Courtney-Brooks, M D
Date approved: April 14, 2011
Description of Study: This study will investigate reasons for non vaccination against human papillomavirus among 18-26 year women who are patients at the Sexually Transmitted Disease Clinic at the Charlottesville/Albemarle Health Department in order to better counsel patients regarding the importance of vaccination.

Study #: 50100
Title of Study: Are Improvements Needed in the Richmond City Health District Family Planning Clinic to Prevent Attrition Among African Americans?
Principal Investigator: Sulola Adekoya, MD
Date approved: May 10, 2011
Description of Study: This study will investigate the reasons that African American females stopped using family planning services in 2010 at the Richmond City

Health Department. The findings will assist in determining improvements or changes to prevent attrition and unplanned pregnancies among aged 18 to 45.

Study #: 50101
Title of Study: WIC Breastfeeding Assessment for Expectant Mothers
Principal Investigator: Esi Amuadu
Date approved: June 29, 2011
Description of Study: This study will survey prenatal and postpartum WIC clients on breastfeeding knowledge, attitudes and practices. The data will be used to strengthen breastfeeding practices in the community.

Study #: 50102
Title of Study: Contribution of Neighborhood Factors to the Risk of Influenza-associated Pediatric Mortality from Seasonal and Pandemic Viruses, 2004-2011 Seasons
Principal Investigator: Joshua Clayton, MPH
Date approved: August 24, 2011
Description of Study: This study will assess whether neighborhood racial composition and socioeconomic position (at the census tract level) affect risk of influenza mortality in children aged less than 18 years.

Study #: 50103
Title of Study: Breastfeeding Views Among Chinese American Women
Principal Investigator: Diana Karczmarczyk
Date approved: August 5, 2011
Description of Study: This study will conduct interviews on breastfeeding practices among Chinese-American Woman between the ages 18 to 40 that work or live in the Alexandria and the broader DC region in order to improve delivery of health department services in a culturally competent manner.

Study #: 50105
Title of Study: A Spatial and Demographic Analysis of the Core Areas of Chlamydia Infection in Virginia
Principal Investigator: Sarah Salino & Carrie Dolan
Date approved: October 19, 2011
Description of Study: This study will analyze secondary historical Chlamydia surveillance data as part of an evaluation of funding allocation for testing.

Study #: 50106
Title of Study: Development of Alternate Methods of Disseminating Information and Providing Prophylaxis to Minority Populations During Mass Prophylaxis Scenario
Principal Investigator: Kevin E. Culbert, D.O., FAAFP
Date approved: October 18, 2011
Description of Study: This study examines the capacity of the regional agencies to respond to public health emergencies (e.g., infectious disease outbreak requiring mass

prophylaxis) within the Lord Fairfax Health District region, with a specific focus on meeting the needs of at-risk populations (e.g., Hispanic/Latino).

Study #: 50107
Title of Study: BRFSS Analysis for Virginia Health Promotion for People with Disabilities (HPPD) Project
Principal Investigator: Donna Gilles, Ed.D
Date approved: November 1, 2011
Description of Study: This study will analyze the Virginia Behavioral Risk Factor Surveillance Survey (BRFSS) data to look at trends and offer descriptive analyses pertaining to the Health Status of Virginians with Disabilities for the years 2010-2011 in order to update the data in the Partnership for People with Disabilities' publication Health Status of Virginians with Disabilities 2007-2009.

Study #: 50108
Title of Study: Environmental Variability and Disease Emergence: Spatial Patterns of Lyme Disease Emergence in Virginia
Principal Investigator: Korine Kolivras, Ph.D
Date approved: November 17, 2011
Description of Study: This study will analyze the patterns of Lyme Disease in order to gain a better understanding of the relationship between landscape environment and Lyme disease incidence. The findings of this study may help the Virginia Department of Health to predict what specific region are more likely to become highly endemic; enabling a more effective geographic focus of surveillance and education resources and efforts.

Study #: 50109
Title of Study: Intergenerational Risk Factors
Principal Investigator: Derek Chapman
Date approved: N/A
Description of Study: This study was submitted to the VDH IRB for review, but IRB action was not taken due to a question regarding whether the study PI is requesting a review as a VDH contractor or as a Virginia Commonwealth University faculty member.

Study #: 50110
Title of Study: Parental Characteristics of Teen Births Resulting from Sex with an Older Partner, 2000-2009
Principal Investigator: Gandarvaka Gray
Date approved: December 1, 2011
Description of Study: This study will identify parental characteristics associated with teen births resulting from sex with an older partner in Virginia. Study results will inform teenage pregnancy prevention efforts by identifying a high risk group within the population and neighborhood characteristics that will allow for targeted efforts by place and population group.

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:

VDH IRB 2011		
Committee Members	**Qualifications for Service**	**Institutional Affiliation**
IRB CHAIR		
Diane Helentjaris	M.D., MPH in Health Management and Policy, Director, Office of Family Health Services,	Virginia Department of Health
VOTING MEMBERS		
J. Elisha Burke	Rev., Dr., and Director, Men's Health and Wellness Ministry	Baptist General Convention of Virginia
Ana Lizzette Colon	M.P.H. in Epidemiology & Regional Surveillance Coordinator	Virginia Department of Health, Eastern Region Field Office
Bethany J. Geldmaker	Ph.D. in Nursing & Child Health Care Consultant	Virginia Department of Health
Gail J. Jennings	Ph.D. in Psychology & Program Director, Virginia Breast and Cervical Cancer Early Detection Program	Virginia Department of Health
Janice Hicks Vice Chair	Ph.D. in Social Policy and Social Work	Virginia Department of Health
David H. Trump	M.D., M.P.H., FACPM and Director, Peninsula Health District	Virginia Department of Health, Peninsula Health District
ALTERNATE MEMBERS		
Vacant		

IV. A COPY OF THE MINUTES OF ANY COMMITTEE MEETINGS CONDUCTED: See attached

Virginia Department of Health
Institutional Review Board

MINUTES

January 10, 2011
10:30 AM – 12:30 PM

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

Members Absent: None

Guests: Susan Spain

General Items/Announcements:

- The meeting convened at 10:47 AM. A quorum was present.

- Announcements
  - Continuing Education Reminder!
  - The VDH IRB will be transitioning from the Office of Minority Health and Health Equity to the Office of Family Health Services some time in the next several months. There is a possibility that Susan Spain will be providing oversight for the OFHS.

- Minutes from the October meeting were unanimously approved.

- VDH IRB Meeting dates for 2011:
  - April 11 (Gail will not be available and Susan Spain will not be available – will inquire about a change in date)
  - July 11
  - October 3

PRESENTATION OF NEW PROTOCOLS – EXEMPTION REVIEW:

Study #:	50090
Title of Study:	Underreporting of Vibrio vulnificus Infections in the Chesapeake Bay Area
Principal Investigator:	Peter S. J. Lees, Ph.D.
Primary Reviewer:	David Trump
Discussion:	None
Description of Action:	Unanimously Approved

Study #:	50091
Title of Study:	The Effectiveness of Point of Care Lead Testing in WIC Clinics with Portable Analyzers in Improving Blood Lead Screening Rates and Follow-up Time Among Children at Risk for Lead Poisoning
Principal Investigator:	Walling, M., Brown, M.J., and Kennedy, C.
Primary Reviewer:	Elisha Burke
Discussion:	None
Description of Action:	Unanimously Approved

Study #:	50093
Title of Study:	Behavioral Risk Factor Surveillance System (BRFSS)

Principal Investigator: Susan Kennedy Spain
Primary Reviewer: Bethany Geldmaker
Discussion: None
Description of Action: Unanimously Approved

Study #: 50095
Title of Study: Educating Future Health Providers to Serve Rural Populations
Principal Investigator: Janet L. McDaniel, Ph.D.
Primary Reviewer: Reviewed At Board Meeting
Discussion: None
Description of Action: Unanimously Approved

PRESENTATION OF NEW PROTOCOLS - EXPEDITED REVIEW:

Study #: 40123
Title of Study: Evaluation of Host Immune Responses to Hepatitis B Vaccine Among Patients Vaccinated in Response to Hepatitis B Outbreak Investigation
Principal Investigator: Thomas John Bender. MD, PhD
Primary Reviewer: David Trump
Discussion: None
Description of Action: Unanimously Approved

Study #: 40124
Title of Study: Latinas' Contraception Experience and Planning (LCEP)
Principal Investigator: Jacqueline M. McGrath
Primary Reviewer: Bethany Geldmaker
Discussion: None
Description of Action: Unanimously Approved

Study #: 40125
Title of Study: The Vaginal Microbiome: Disease, Genetics and the Environment
Principal Investigator: Gregory Buck
Primary Reviewer: Ana Colon
Discussion: None
Description of Action: Unanimously Approved

PRESENTATION OF NEW PROTOCOLS - FULL BOARD REVIEW:

None.

CONTINUATION REVIEWS/RENEWALS:

Study #: 40002
Title of Study: Follow-up of CPS-II Participants through Linkage with State Cancer Registries
Principal Investigator: Susan M. Gapstur, Ph.D. MPH
Discussion: None
Description of Action: Unanimously Approved

Study #: 40005
Title of Study: Role of Environment and Diet in Increased Prostate Cancer Mortality in African Americans
Principal Investigator: M. Norman Oliver, M.D.

Discussion: None
Description of Action: Study completed and closed.

Study #: 40015
Title of Study: Family Health Study (Validation of a Family History of Cancer Questionnaire for Risk Factor Surveillance)
Principal Investigator: Gordon B. Willis, Ph.D.
Discussion: None
Description of Action: Unanimously Approved

Study #: 40095
Title of Study: National Study of Determinants of Early Diagnosis, Prevention and Treatment of TB
Principal Investigator: Suzanne Keller, M.A.
Discussion: None
Description of Action: Unanimously Approved

Study #: 40098
Title of Study: Invasive MRSA in South Hampton Roads
Principal Investigator: Batrina Martin
Discussion: None
Description of Action: Study completed, will be closed pending receipt and review of study summary report.

OTHER (MINOR MODIFICATIONS, ETC):

Study #: 40068
Title of Study: Medical Monitoring Project
Principal Investigator: Dena Bensen, Celestine Buyu
Type of Review: Minor Modification
Description: CDC protocol has been modified to include updates to both the English and Spanish questionnaires and the medical records abstraction forms.
Discussion: None.
Description of Action: Unanimously Approved.

Study #: 40069
Title of Study: Virginia Pregnancy Risk Assessment Monitoring System (VA-PRAMS)
Principal Investigator: Janice Hicks, Ph.D.
Type of Review: Minor Modification
Description: In a previous modification, the PI added 12 questions pertaining to H1N1. Now that H1N1 and seasonal flu vaccines have been combined, these questions no longer need to be asked separately, and thus the PI is requesting a minor modification to combine these items.
Discussion: None.
Description of Action: Unanimously Approved.

Study #: 40095
Title of Study: National Study of Determinants of Early Diagnosis, Prevention and Treatment of TB
Principal Investigator: Suzanne Keller, M.A.
Type of Review: Incident Report – Adverse Event

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

Discussion: None.

Description of Action: Corrective action plan was Unanimously Approved.

Study #: 40105

Title of Study: Virginia Comprehensive Cancer Control Project

Principal Investigator: Jean Gaare Eby, ScD, James Martindale, Ph.D. and Christina Sheffield

Type of Review: Minor Modification

Description: The PI is requesting that the following individuals be added as sub-investigator: Aaron Pannone, MS, Department of Public Health Sciences, School of Medicine, University of Virginia

Discussion: None.

Description of Action: Unanimously Approved.

Study #: 40108

Title of Study: Enhanced Label to Promote Patient Understanding and Use

Principal Investigator: Michael S. Wolf, Ph.D., MPH

Type of Review: Minor Modification

Description: The PI is requesting a change in the Project Coordinator, from Anjali Pandit to Kathryn Davis. In addition, the PI is requesting the addition of Spanish speakers to the study. All other aspects of the protocol will remain the same. Consent documents have been translated into Spanish and were included in the minor modification request.

Discussion: None.

Description of Action: Unanimously Approved.

Study #: 40115

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

Principal Investigator: Laura Jensen

Type of Review: Minor Modification

Description: The PI is requesting a change in the survey instrument and protocol. The PI would like to insert a "Phase Two" between the two previously approved phases of the study. The new phase will include survey research at public breast cancer awareness events sponsored by health care providers and community organizations in the targeted area. Participation in the survey is voluntary and responses are anonymous.

Discussion: None.

Description of Action:	Unanimously Approved.
Study #:	40119
Title of Study:	Understanding Oral Health and Health Care in Lenowisco and Cumberland Plateau Health Districts
Principal Investigator:	Sarah Raskin
Type of Review:	Minor Modification
Description:	The PI is requesting a change in the wording of the recruitment materials for parents and to add graphics.
Discussion:	None.
Description of Action:	Unanimously Approved.
Study #:	50064
Title of Study:	Behavioral Risk Factor Surveillance Survey (BRFSS) Study
Principal Investigator:	Peggy Brown Paviour, M.S., CHES
Type of Review:	Minor Modification
Description:	The PI is requesting two additional years (2008-2009) of BRFSS data in order to have the most recent data to look at trends. The original request was for the years 1989 – 2007. In addition, the PI would like to add a co-investigator to the study (Michael Marquardt) in replacement of the original co-investigator, Drew Saylor, who is no longer working on the study.
Discussion:	None.
Description of Action:	Unanimously Approved.
Study #:	50088
Title of Study:	Grandparent-Headed Families and Virginia WIC: An Examination of Service Awareness, Utilization and Delivery
Principal Investigator:	Megan L. Doblin-MacNab, PhD, LMFT
Type of Review:	Minor Modification
Description:	The PI is requesting amendments to the following documents: 1) Protocol – the PI has added to t he protocol that in addition to the "Receipt of Compensation" form, the participant is also being asked to initial the receipt; 2) Consent Form – amended the consent form to include information about the requirement that the participant initial the receipt form; 3) Data Collection Instrument – minor edits requested in the wording of several questions and included a script for the interviews.
Discussion:	None.
Description of Action:	Unanimously Approved.

Meeting was adjourned at 12:14 PM.

Virginia Department of Health
Institutional Review Board

MINUTES

April 18, 2011
10:30 AM – 12:30 PM

Members Present: Kathy Wibberly (Chair), Elisha Burke (arrived at 10:55 AM), Ana Colon, Bethany Geldmaker, David Trump, Gail Jennings

Members Absent: None

Guests: Susan Spain, Cheryl Henry, Tywanda Bolden

General Items/Announcements:

- The meeting convened at 10:35 AM. A quorum was present.

- Announcements
  - Continuing Education Reminder!
    - Bethany took part in an MCH.com webcast training on March 25th on pediatric trial Exceptions from informed consent and shared some of what she learned.

  - The VDH IRB will be transitioning from the Office of Minority Health and Health Equity to the Office of Family Health Services in the next month. Susan Spain will be the new Chair of the VDH IRB, Cheryl Henry will be co-chair, and Tywanda Bolden will be providing administrative support. Kathy will continue to provide some continuity as a member until all new member appointments have been made and the transition is complete. The next meeting will take place in a conference room TBD by Susan.

- Minutes from the January meeting were unanimously approved.

- VDH IRB Meeting dates for the remainder of 2011:
  - July 11
  - October 3

PRESENTATION OF NEW PROTOCOLS – EXEMPTION REVIEW:

Study #:	50092
Title of Study:	Assessment of Educational, Clinical and Advocacy Needs Related to Cancer in Southside and Southwest Counties of Virginia
Principal Investigator:	Gordon Dean Ginder, MD
Primary Reviewer:	Gail Jennings
Discussion:	The PI submitted a protocol for review on January 28th. It was reviewed and deemed to be approvable conditioned upon an acceptable response to three issues: 1) PI needs to provide copies of the research instruments; 2) PI needs to identify procedures for protecting the confidentiality of information to be collected and 3) PI needs to document or identify other IRBs that have reviewed the protocol. The PI has not provided a response.
Description of Action:	An email will be sent to the PI to determine if the file should remain active/open or if it should be closed.

Study #: 50096
Title of Study: Foodscapes, Inequality and Disease: Interrelationships between Food Environment and Public Health in Charlottesville, VA
Principal Investigator: Rebecca M. Tippett, PhD
Primary Reviewer: Elisha Burke
Discussion: None
Description of Action: Unanimously Approved

Study #: 50097
Title of Study: Chronic Disease Burden Report for Virginia Department of Health
Principal Investigator: Henry J. Carretta, PhD, MPH
Primary Reviewer: Bethany Geldmaker
Discussion: None
Description of Action: Unanimously Approved

Study #: 50098
Title of Study: Physicians Survey of Beliefs and Practices Pertaining to Sports Related Concussions
Principal Investigator: Witemba Kabange
Primary Reviewer: Gail Jennings
Discussion: None
Description of Action: Unanimously Approved

Study #: 50099
Title of Study: Human Papillomavirus Vaccination: Barriers to Vaccination Among Young Adult Women
Principal Investigator: Madeleine Courtney-Brooks, MD
Primary Reviewer: Elisha Burke
Discussion: None
Description of Action: Unanimously Approved

PRESENTATION OF NEW PROTOCOLS - EXPEDITED REVIEW:

Study #: 40126
Title of Study: WIC Program Assessment
Principal Investigator: Mary Beth Dunkenberger
Primary Reviewer: Ana Colon
Discussion: None
Description of Action: Unanimously Approved

Study #: 40127
Title of Study: Evaluation of the text4baby Mobile Pre-natal Health Program
Principal Investigator: W. Douglas Evans, PhD
Primary Reviewer: David Trump
Discussion: None
Description of Action: Unanimously Approved

Study #: 40128
Title of Study: Guided Imagery Effects on Pregnancy Symptoms and Outcomes
Principal Investigator: Nancy Jallo
Primary Reviewer: Bethany Geldmaker
Discussion: None

Description of Action: Unanimously Approved

Study #: 40129
Title of Study: Analysis of Animal Exposure in South East Virginia
Principal Investigator: Hind Baydoun
Primary Reviewer: David Trump
Discussion: None
Description of Action: Unanimously Approved

Study #: 40130
Title of Study: Program for Child to Adult Transition of Sickle Cell Care
Principal Investigator: Wally Smith
Primary Reviewer: Gail Jennings
Discussion: None
Description of Action: Unanimously Approved

Study #: 40131
Title of Study: Project Connnect: Evaluation of a Public Health Partnership to Prevent Violence Against Women
Principal Investigator: Elizabeth Miller, MD, PhD
Primary Reviewer: David Trump
Discussion: This protocol was originally submitted for exemption review. It was felt that this was not appropriate and the PI was asked to resubmit using the expedited review form.
Description of Action: Unanimously Approved

Study #: 40132
Title of Study: Smoking Cessation During Pregnancy
Principal Investigator: Dr. Linda Bullock
Primary Reviewer: Reviewed At Meeting
Discussion: Discussion centered upon the need for some other questions pertaining to the use of tobacco products and/or substitutes. Several typos and formatting issues were also identified in the survey instrument. A question was also raised regarding the true level of risk since the PI cited another pilot study where "only three calls" were made to the child abuse hotline. It was unclear how many participants there were in the pilot to adequately ascertain whether this was minimal risk.
Description of Action: Unanimously Approved with the following recommendations for the PI's consideration:

- Add a question or two about smokeless tobacco use during the baseline and follow up surveys to ascertain whether smokeless tobacco is potentially used as a substitute for the nicotine patch
- Add a question or two about the use of other tobacco products during the baseline and follow up surveys to ascertain the potential impact of other sources of second hand smoke.
- Proofread the survey instrument for typos and formatting consistencies.

Will also seek clarification from the PI about the "only three calls" question as noted above.

PRESENTATION OF NEW PROTOCOLS - FULL BOARD REVIEW:

None.

CONTINUATION REVIEWS/RENEWALS:

Study #: 30003
Title of Study: Evaluation of a School Based Fluoride Rinse Program
Principal Investigator: Karen Day, Director, Division of Dental Health
Discussion: None
Description of Action: Study completed and closed.

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

Study #: 40064
Title of Study: Epidemiology and Biostatistical Component of the Pratt & Whitney Cohort Mortality and Cancer Incidence Study
Principal Investigator: Gary M. Marsh, PhD
Discussion: None
Description of Action: Unanimously Approved

Study #: 40075
Title of Study: Improving Capture of Chemotherapy Information Using Physician Office Billing
Principal Investigator: Lynn Penberthy
Discussion: Data collection is complete and analyses are under way and available in draft form. Final analyses will be provided in a study summary.
Description of Action: Unanimously Approved.

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

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

Study #: 40098
Title of Study: Invasive MRSA in South Hampton Roads
Principal Investigator: Batrina Martin
Discussion: None
Description of Action: Study complete and closed.

Study #: 40105
Title of Study: Virginia Comprehensive Cancer Control Project
Principal Investigator: Jean Gaare Eby
Discussion: None
Description of Action: Unanimously Approved

Study #: 40106
Title of Study: Forteo Patient Registry
Principal Investigator: Alicia Gilsenan, PhD
Discussion: None
Description of Action: Unanimously Approved

Study #: 40107
Title of Study: Baby Basics Moms Club
Principal Investigator: Merry McKenna
Discussion: None
Description of Action: Unanimously Approved

Study #: 40108
Title of Study: Enhanced Label to Promote Patient Understanding and Use
Principal Investigator: Michael S. Wolf, PhD, MPH
Discussion: None
Description of Action: Unanimously Approved

Study #: 40109
Principal Investigator: Ann L. Kellams, MD, IBCLC, FAAP
Title of Protocol: Prenatal Education Video Study
Discussion: None
Description of Action: Unanimously Approved

OTHER (MINOR MODIFICATIONS, ETC):

Study #: 50088
Title of Study: Grandparent-Headed Families and Virginia WIC: An Examination of Service Awareness, Utilization, and Delivery
Principal Investigator: Megan L. Dolbin-MacNab, Ph.D., LMFT
Type of Review: Minor Modification
Description: The PI is requesting a modification to extend the period of their study through 2010 (which includes being able to access the next two cycles of BRFSS data). A number of the questions for the portion of the project entitled, "Survey - Grandparents Raising Grandchildren" have been revised. The updated version of the survey contains some editing to the phrasing of a number of the survey questions (the content is relatively similar to the previously approved version of the survey). It is also somewhat shorter, which should result in participants spending less time responding to the survey items. The PI has also included a script for the interviewers. With the addition of the interviewer instructions, the revised survey will be easier for participants to understand and follow.
Discussion: None.
Description of Action: Unanimously Approved.

Study #: 40069
Title of Study: Virginia Pregnancy Risk Assessment Monitoring System (VA-PRAMS)
Principal Investigator: Janice Hicks, PhD
Type of Review: Minor Modification
Description: The PI is requesting a modification to extend the study period through April 2012. The PI received a grant renewal for another grant cycle.
Discussion: None.
Description of Action: Unanimously Approved.

Study #: 40105
Title of Study: Virginia Comprehensive Cancer Control Project
Principal Investigator: Jean Gaare Eby
Type of Review: Minor Modification
Description: The PI is requesting a modification to extend the period of their study through 2010 (which includes being able to access the next two cycles of BRFSS data).
Discussion: None.
Description of Action: Unanimously Approved.

Study #: 40106
Title of Study: Forteo Patient Registry
Principal Investigator: Alicia Gilsenan, Ph.D.
Type of Review: Minor Modification
Description: The PI is requesting a modification to include two new consent forms, one for proxies and one for guardians. The addition of the two new consent forms will only have a minimal impact on the study protocol and procedures, and only for cases where a proxy or guardian consent form are required. All procedures for enrolling the patient, securely maintaining patient data, and performing the annual data linkage with participating cancer registries have remain unchanged, except in rare instances where an enrollee is unable to sign the patient consent form. In those cases, the enrollee can request a proxy or guardian consent form, and the proxy or guardian will sign in the place of the enrollee. All other procedures remain unchanged. The language in the patient consent form has not changed and will still be used in almost all cases, except in the instances mentioned above. The privacy and security language in the proxy and guardian consent forms are identical to the language used in the previously approved patient consent form. Additionally, the two new consent forms have been reviewed and approved by the RTI IRB.
Discussion: None.
Description of Action: Unanimously Approved.

Study #: 40108
Title of Study: Enhanced Label to Promote Patient Understanding and Use
Principal Investigator: Michael S. Wolf, Ph.D. MPH
Type of Review: Minor Modification
Description: The PI is requesting a modification to expand the eligibility criteria for patients wanting to participate in the study. Patients will no longer have to have a diagnosis of diabetes or hypertension to participate. Any patient aged 30 years or older who is receiving at least 2 medicines from the NovaScript pharmacy will now be eligible.
Discussion: None.
Description of Action: Unanimously Approved.

Study #: 40126
Title of Study: WIC Program Assessment
Principal Investigator: Mary Beth Dunkenberger
Primary Reviewer: Ana Colon
Type of Review: Minor Modification
Description: The PI is requesting a modification to update questions on the survey instruments and also note the addition of an online option for survey respondents. The researchers have decided to offer the survey online in addition to delivering the survey via US mail. Following the Pilot Survey there were changes made to the survey instrument originally submitted. Changes

made were: Q3 and Q4 were combined and simplified into a matrix question. Question 4 was added asking the Department of Social Service Office which referred the foster child. Question 20, an open-ended question was added to assess the experience of foster parents who have utilized WIC services in the past. Question 26 was added to determine if the foster parent and the foster child were kin. Question 38 was added requesting information regarding the county or city in which the foster family resided.

Discussion: None.

Description of Action: Unanimously Approved.

Meeting was adjourned at 1:04 PM.

Virginia Department of Health
Institutional Review Board

MINUTES

July 11, 2011
10:30 AM – 12:00 PM

Members Present: Kathy Wibberly, Diane Helentjaris, Janice Hicks, Ana Colon, Bethany Geldmaker (arrived at 10:35), David Trump, and Gail Jennings

Members Absent: Elisha Burke

Administrative Support: Tywanda Bolden and Susan Kennedy Spain

General Items/Announcements:

- The meeting convened at 10:35 AM. A quorum was present.

- Announcements
  - Kathy Wibberly last time conducting the IRB meeting.
  - Transition of VDH IRB to Office of Family Health Services effective July 12, 2011

- Minutes from the April meeting were unanimously approved.

- VDH IRB Meeting dates for the remainder of 2011:
  - October 3 (Please remember to bring your calendar to set dates for 2012 meetings)

PRESENTATION OF NEW PROTOCOLS – EXEMPTION REVIEW:

Study #:	50100
Title of Study:	Are There Improvements needed in the Richmond City Health District Family Planning Clinic to Prevent Attrition Among African Americans?
Principal Investigator:	Dr. Sulola Adekoya
Primary Reviewer:	Ana Colon
Discussion:	Telephone survey of clients who received services in 2009 who have not accessed services in 2010. Discussion regarding moved location of Richmond City Health District and whether this may be a factor for attrition. IRB members recommend that PI consider this and add questions regarding whether interviewed clients know the clinic has moved, what would make them return.
Description of Action:	Approved with recommendations.

Study #:	50101
Title of Study:	WIC Breastfeeding Assessment for Expectant Mothers
Principal Investigator:	Esi Amuadu
Primary Reviewer:	Elisha Burke
Discussion:	English/Spanish data collection project to assess WIC clients (pre-natal and post partum) intention to breast feed. Discussion focused on the need to ask mothers' questions regarding milk storage and to clarify the type of space that is available for lactation activities.
Description of Action:	Approved with recommendations.

PRESENTATION OF NEW PROTOCOLS – EXPEDITED REVIEW:

Study#:	40133
Title of Study:	What Do Parents Think About the Best Ways to Prevent Illness in their Children and About Vaccinations
Principal Investigator:	Eleanor S. Cantrell, MD and John Dreyzehner, MD, MPH
Primary Reviewer:	Bethany Geldmaker
Discussion:	Multi-mode data collection with Flu Survey and Focus Groups for parents/legal guardians for families in Wise, Lee, Scott, Dickerson, Russell, Tazewell, and Buchanan Counties and City of Norton. Coverage targets were not met for these communities for H1N1 vaccination. Participants will be recruited by school nurses and identified as either parents that vaccinated or parents that did not. Approval pending 4 conditions: 1) Title of protocol not consistent, 2) PI CV requested, 3) study contains objective pertaining to routine child vaccinations with no survey questions or clear focus groups questions regarding this objective, and 4) protocol describes gift card as subject compensation while informed consent refers to benefit and states no compensation. Recommendations to include race/ethnicity questions in survey be broader to reflect diversity, and for the PI to consider a thank you gift or incentive for school nurses. All conditions met.
Description of Action:	Approved with recommendations.

Study#:	40134
Title of Study:	Linkage to Virginia Cancer Registry for an Ongoing Retrospective Study of Satellite Workers
Principal Investigator:	Joseph K. McLaughlin, Ph.D
Primary Reviewer:	David Trump
Discussion:	None.
Description of Action:	Approved.

PRESENTATION OF NEW PROTOCOLS – FULL BOARD REVIEW:
NONE.

CONTINUATION REVIEWS/RENEWALS"

Study #:	40015
Title of Study:	Family Health Study (Validation of a Family History of Cancer Questionnaire for Risk Factor Surveillance
Principal Investigator:	Louise Wideroff, Ph.D., MSPH
Discussion:	Conclusions provided.
Description of Action:	Study completed and closed.

Study #:	40027
Title of Study:	Evaluation of the text4baby Mobile Pre-natal Health Program
Principal Investigator:	Fern R. Hauck, M.D., M.S.
Discussion:	None
Description of Action:	Unanimously approved.

Study #: 40032
Title of Study: Interview of Persons from which Enteric Bacterial Isolates have been Cultured With Uncommon Antimicrobial Resistance Patterns
Principal Investigator: Dr. Ezra Barzilay
Discussion: None
Description of Action: Unanimously approved.

Study #: 40039
Title of Study: Central Brain Tumor Registry of the United States (CBTRUS)
Principal Investigator: Bridget J McCarthy, PhD.
Discussion: None
Description of Action: Unanimously approved.

Study #: 40052
Title of Study: Southern Community Cohort Study
Principal Investigator: William J. Blot, PhD
Discussion: None
Description of Action: Unanimously approved.

Study #: 40089
Title of Study: Hampton Roads VDH/VIMS Clam Project
Principal Investigator: Howard Kator, PhD.
Discussion: None.
Description of Action: Unanimously approved.

Study #: 40092
Title of Study: Flight Attendants Health Study: The Incidence of Breast and Other Cancers Among Female Flights Attendants
Principal Investigator: Lynne Pinkerton, MD, MPH
Discussion: One drop-out due to no incidence, but self report concerns.
Description of Action: Unanimously approved.

Study#: 40099
Title of Study: Evaluation of Vestibular Deficits and Interventions in Hearing Impaired Infants
Principal Investigator: Kelly Dodson, MD
Discussion: Lost funding, study never started.
Description of Action: Study closed.

Study#: 40110
Title of Study: Improving the Management of Tuberculosis in Patients from Virginia Using the Whole Blood Bactericidal Assay
Principal Investigator: Scott K Heysell, MD, MPH
Discussion: None
Description of Action: Unanimously approved.

Study#: 40111
Title of Study: The Use of Progesterone by Obstetric Providers in Richmond, Virginia
Principal Investigator: Cheryl Bodamer, PhD, MPH
Discussion: Conclusions provided.
Description of Action: Study completed and closed.

OTHER (MINOR MODIFICATIONS, ETC):

Study #:	40110
Title of Study:	Improving the Management of Tuberculosis in Patients from Virginia Using the Whole Blood Bactericidal Assay
Principal Investigator:	Scott K Heysel, MD, MPH
Type of Review:	Minor Modification
Description:	The PI requested a modification to the consent form document. The original document contained a typographical/sentence sequencing error that has been corrected in the revised document.
Discussion:	None.
Description of Action:	Unanimously approved.

Study #:	40114
Title of Study:	Virginia Youth Risk Behavior Survey (The Virginia Youth Survey Project)
Principal Investigator:	Janice M. Hicks, PhD
Type of Review:	Minor Modification
Description:	The PI requested a modification that identifies the specific set of state added questions that will be used for the survey. The full set of optional questions was included in the original protocol.
Discussion:	None.
Description of Action:	Unanimously approved.

Study#:	50084
Title of Study:	Influenza Incidence Surveillance Project
Principal Investigator:	Katie Kurkjian
Primary Reviewer:	Bethany Geldmaker
Description:	PI requested modification to extend the project period to May 31, 2012, to identify a new project coordinator, and to remove two components from the original protocol. The two components include the tracking and aggregate reporting of the number of persons with acute respiratory illness and the rapid influenza antigen testing.
Discussion:	None.
Description of Action:	Unanimously approved.

Study#:	50089
Title of Study:	Compendium of Best Practices and Analyses of Gaps and Barriers to their Widespread Adoption
Principal Investigator:	Janet L McDaniel, PhD
Primary Reviewer:	Gail Jennings
Description:	The PI requested a modification to extend the project period until September 31, 2011.
Discussion:	None.
Description of Action:	Unanimously approved.

Meeting was adjourned at 12:05 PM.

Virginia Department of Health
Institutional Review Board

MINUTES

October 3, 2011
10:30 AM – 12:35 PM

Members Present: Diane Helentjaris, Elisha Burke, Ana Colon, David Trump, Bethany Geldmaker, Gail Jennings (arrived 10:34), Susan Kennedy Spain, Tywanda Bolden

Members Absent: None

General Items/Announcements:

- The meeting convened at 10:35 AM. A quorum was present.
- Minutes from the July meeting were unanimously approved.
- VDH IRB Members requested that IRB forms be revised to include a field for PI's to provide information regarding IRB submission/approval from a university or private IRB. Forms will be revised in October 2011.
- VDH IRB Members recommended that a new member be added that has expertise in GIS and spatial analysis since there has been an increase in these types of protocols. This type of expertise is needed for these types of protocols.
- VDH IRB Meeting dates for Year 2012, at 10:30-12:30:
  January 9
  April 2
  July 9
  October 1

PRESENTATION OF NEW PROTOCOLS – EXEMPTION REVIEW:

Study#:	50102
Title of Study:	Contribution of Neighborhood Factors to the Risk of Influenza associated Pediatric Mortality from Seasonal and Pandemic Viruses, 2001-2011 Seasons
Principal Investigator:	Joshua Clayton, MPH
Primary Reviewer:	Elisha Burke
Discussion:	Secondary data analysis of public use influenza data, 2001-2011. Deaths for 18 and under. No contact with families.
Description of Action:	Unanimously Approved

Study#:	50103
Title of Study:	Breastfeeding Views Among Chinese American Women
Principal Investigator:	Diana Karczmarczyk, MPH, CHES
Primary Reviewer:	Bethany Geldmaker
Discussion:	Additional information requested regarding recruitment and sample size.
Description of Action:	Unanimously approved with the following conditions

Study#:	50104
Title of Study:	The Association Between Maternal Obesity and Adequacy of Prenatal Care
Principal Investigator:	Saba Masho, MD, MPH
Primary Reviewer:	David Trump
Discussion:	Well written protocol.
Description of Action:	Unanimously approved as expedited protocol. New protocol # 40137. Protocol # 50104 has been deleted.

Study#:	50105
Title of Study:	A Spatial and Demographic Analysis of the Core Areas of Chlamydia Infection in Virginia
Principal Investigator:	Sarah Salino & Carrie Dolan
Primary Reviewer:	Ana Colon
Discussion:	It was not clear from the protocol whether the project had been submitted to William & Mary's IRB. VDH IRB has asked for clarification and documentation of approval, if submitted. Discussion regarding whether data would be received already geo-coded for spatial clustering analysis to ensure cases could not be identifiable at the address level. VDH IRB has asked PI to provide confirmation.
Description of Action:	Unanimously Approved

PRESENTATION OF NEW PROTOCOLS – EXPEDITED REVIEW:

Study#:	40135
Title of Study:	Impact of a Workplace Colorectal Cancer Screening Awareness Program
Principal Investigator:	Resa M. Jones, MPH, Ph.D
Primary Reviewer:	Ana Colon, MPH
Discussion:	Protocol provides clear documentation regarding study plan and methods, measures to keep the information confidential and provides documentation regarding data security. The protocol included a sample of a consent form, questionnaire and materials to be used for employee knowledge and attitude assessment. VDH IRB would like documentation regarding submission/approval from VCU IRB.
Description of Action:	Unanimously Approved.

Study#:	40136
Title of Study:	Social-spatial Risk and Protective Mechanisms in Urban Adolescent Substance Use
Principal Investigator:	Michael J Mason, Ph.D
Primary Reviewer:	Bethany Geldmaker, Ph.D., PNP
Discussion:	None
Description of Action:	Unanimously Approved.

PRESENTATION OF NEW PROTOCOLS – FULL BOARD REVIEW: NONE

CONTINUATION REVIEWS/RENEWALS"

Study#:	40015©
Title of Protocol:	Family Health Study (Validation of a Family History of Cancer Questionnaire for Risk Factor Surveillance
Principal Investigator:	Gordon B. Willis, Ph.D.
Discussion:	Short summary provided.
Description of Action:	Study completed and closed.

Study#:	40039©
Title of Protocol:	Central Brain Tumor Registry of the Unites States
Principal Investigator:	Bridget J McCarthy, Ph.D.
Discusssion:	PI provided copies of numerous reports and research articles.
Description of Action:	Study completed and closed.

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

Study#:	40068
Title of Protocol:	Medical Monitoring Project
Principal Investigator:	Dena Benson, MPH
Discussion:	None
Description of Action:	Unanimously Approved.

Study#:	40069
Title of Protocol:	Virginia Pregnancy Risk Assessment Monitoring System (VA-PRAMS)
Principal Investigator:	Derek Chapman, Ph.D
Discussion:	None
Description of Action:	Unanimously Approved.

Study#:	40076
Title of Protocol:	Black Women's Health Study: A Follow-up Study
Principal Investigator:	Lynn Rosenberg, Sc.D.
Discussion:	59,000 African-American women included in study. PI submitted s summary of recent literature and findings from study.
Description of Action:	Unanimously Approved.

Study#:	40083
Title of Protocol:	See Ya Later Flu-A-Gator: A childhood influenza vaccination project (renamed 2009 – formerly named "Flu Clues")
Principal Investigator:	John Dreyzehner, MD, MPH, FACOEM
Discussion:	Summary provided on recent literature and findings. Total anticipated number of participants for 2011/2012 will be 6, 000 individuals. Continuation and modification review needed because principal investigator has changed.
Description of Action:	Unanimously Approved.

Study#: 40086©
Title of Protocol: Oral Health Assessment of Virginia Elders
Principal Investigator: Karen Day, DDS, MS, MPH
Discussion: Need a final summary of the study. Requested summary from PI.
Description of Action: Study completed and closed.

Study#: 40093
Title of Protocol: Baby Basics Southwest Virginia
Principal Investigator: Merry McKenna
Discussion: 60 participants entered into study to date.
Description of Action: Unanimously Approved.

Study#: 40094©
Title of Protocol: Virginia Youth Survey
Principal Investigator: Janice Hicks, Ph.D.
Discussion: None. Study never started. Protocol #40114 is same PI/Same Protocol.
Description of Action: Unanimously Approved.

Study#: 40096
Title of Protocol: An Examination of Uninsured and Insured Cancer Patients in Virginia
Principal Investigator: Cathy J. Bradley, Ph.D
Discussion: 84, 540 study participants. Provided summary of progress and information regarding recent publications.
Description of Action: Unanimously Approved.

Study#: 40101
Title of Protocol: Cancer Epidemiology in Adventists – A low risk group
Principal Investigator: Gary E. Fraser
Discussion: No new subjects enrolled. Provided summary of recent publications, 11 total.
Description of Action: Unanimously Approved.

Study#: 40102
Title of Protocol: Analysis of Urethral Exudates in Acute Gonorrhea
Principal Investigator: Alison Criss, Ph.D.
Discussion: Two subjects enrolled to date.
Description of Action: Unanimously Approved.

Study#: 40104©
Title of Protocol: Health Equity Education, Awareness and Advocacy through Utilizing Unnatural Causes: Is Inequality Making Us Sick?
Principal Investigator: Anika Tahirah Richards
Discussion: None. Summary provided.
Description of Action: Study completed and closed.

Study#:	40111©
Title of Protocol:	The Use of Progesterone By Obstetric Providers in Virginia
Principal Investigator:	Cheryl Bodamer, Ph.D., MPH, RN
Discussion:	None. Summary provided.
Description of Action:	Study completed and closed.

Study #:	40112©
Title of Protocol:	Evaluation of the Syphilis Reactor Grid
Principal Investigator:	Christine Flavin, MPH
Discussion:	None. No summary provided.
Description of Action:	Study completed and closed.

Study#:	40113©
Title of Protocol:	Oral Health Assessment of Virginia Adults at the Mission of Mercy (MOM) Projects
Principal Investigator:	Karen Day, DDS, MS, MPH
Discussion:	None. Summary provided.
Description of Action:	Study completed and closed.

Study#:	40114©
Title of Protocol:	Virginia Youth Risk Behavior Survey (The Virginia Youth Survey Project)
Principal Investigator:	Janice Hicks, Ph.D
Discussion:	During this time of the meeting zero subject were entered into the study, shortly after principal investigator requested reopened
Description of Action:	Reopened

Study#:	40115
Title of Protocol:	Exploring Risk and Perceptions of Risk in the Diagnosis of Breast Cancer in Rural Southwest Virginia
Principal Investigator:	Laura Jensen
Discussion:	To date, 50 participants participated in key informant interviews and 300 survey respondents. Continuation for the purpose of continued access to data collected and analysis.
Description of Action:	Unanimously Approved.

Study#:	40116
Title of Protocol:	Health Effects: Air Pollution and Adverse Birth Outcomes in the U.S
Principal Investigator:	Naresh Kumar, Ph.D
Discussion:	None
Description of Action:	Unanimously Approved.

Study#:	40117
Title of Protocol:	Community Outreach and Volunteer Training: Medical Reserve Corps Study
Principal Investigator:	Jack Harrald, Ph.D
Discussion:	42 subjects enrolled.
Description of Action:	Unanimously Approved.

Study#: 40118
Title of Protocol: Cancer Risk among Firefighters and Emergency Service Rescuers and Officers Exposed to the World Trade Center Disaster
Principal Investigator: David J Prezant, M.D.
Discussion: Data received on 29, 758 records from Cancer Registry.
Description of Action: Unanimously Approved.

Study#: 40119*
Title of Protocol: Understanding Oral Health & Health Care in Lenowisco & Cumberland Plateau Health Districts
Principal Investigator: Sarah Raskin, MPH
Discussion: 74 children enrolled.
Description of Action: Unanimously Approved.

Study#: 40120
Title of Protocol: Endometrial Cancer in Virginia
Principal Investigator: Madeleine Courtney-Brooks, MD
Discussion: The records of 16, 113 patients diagnosed with endometrial cancer in Virginia from 1988-2009 were received.
Description of Action: Unanimously Approved.

OTHER (MINOR MODIFICATIONS, ETC):

Study#: 40119*
Title of Protocol: Understanding Oral Health and Health Care in Lenowisco and Cumberland Plateau Health District
Principal Investigator: Sarah Raskin, MPH
Type of Review: Minor Modification
Description: Change in the recruitment process to include a two-step recruitment process to 1) Distribute a document to obtain parents' consent for PI to contact them by phone at the number provided on their dental procedure consent form and 2) To call parents to describe the study by phone using verbiage already approved by the IRB, and then invite parents to participate.
Description of Action: Unanimously Approved.

Study#: 40040*
Title of Protocol: Cohort Cancer Registry Follow-Up Study
Principal Investigator: Meir Stampfer, M.D., PH.
Type of Review: Minor Modification
Description: Addition of variable (hospital/provider name and hospital address) that is collected from the Virginia Cancer in order to obtain paraffin-embedded tissue specimens on deceased participants. No consent required and most pathology departments are willing to release the information on decedents without consent.
Discussion: None.
Description of Action: Unanimously Approved.

Study#	40110
Title of Protocol:	Improving the Management of Tuberculosis in Patients from Virginia Using the Whole-Blood Bactericidal Assay|
Principal Investigator:	Scott K Heysell
Type of Review:	Minor Modification
Description:	Enrollment has been limited by investigator inability to travel of distant health department across the state to enroll subjects with tuberculosis. Each health department is equipped with video/ teleconference which would allow enrollment using UVA video/ equipment and preserve face-to-face interaction. Blood draw for use in the assay has also been limited by transport of the specimen to UVA from more distant health departments. As an alternative, leftover serums from the sample drawn for clinical drug level testing can be used, shipment of the leftover sample will be more easily shipped to UVA/ Houpt lab.
Discussion:	None.
Description of Action:	Unanimously Approved.

Study#:	50084
Title of Protocol:	Influenza Incidence Surveillance Project
Principal Investigator:	Katie Kurkjian
Type of Review:	Minor modification
Description:	The extension of the project period; the identification of a new Project Coordinator and the elimination of two components from the original protocol.
Discussion:	None.
Description of Action:	Unanimously Approved.

Study#:	50088
Title of Protocol:	Grandparent-Headed Families and Virginia WIC: An Examination of Service Awareness, Utilization and Delivery
Principal Investigator:	Megan Dolbin-MacNab, Ph.D., LMFT
Type of Review:	Minor Modification
Description:	Refine the inclusion criteria and adjusting the sample size; change survey .vt.edu to Qualtrics; discontinue online survey participant incentives; reduce time to complete survey from 30 to 20 minutes and to update recruitment materials with new information; adjust recruitment materials to change in inclusion criteria; revision of consent document to specify that target grandchild must be aged 5 or under and cannot be currently enrolled in WIC; and minor modification of survey questions.
Discussion:	None.
Description of Action:	Unanimously Approved.

Meeting was adjourned at 12:35 PM.