

**REPORT TO THE COMMISSIONER:
ACTIVITIES OF
THE VIRGINIA DEPARTMENT OF HEALTH
INSTITUTIONAL REVIEW BOARD
CALENDAR YEAR 2012**

Submitted by

**Dev Nair, PhD, MPH
Chair**

Virginia Department of Health Institutional Review Board

REPORT TO THE COMMISSIONER: ACTIVITIES OF THE VDH IRB FOR CALENDAR YEAR 2012

Regulations for the conduct of human research, developed and approved by the Board of Health, became effective on July 1, 1993. According to those regulations, prior to the initiation of a human research project by any institution or agency funded or licensed by the health department, a description of the proposed human research project shall be submitted to a research review committee for review and approval. The Virginia Department of Health (VDH) subsequently appointed an Institutional Review Board (IRB). In addition, a policy document, *The Institutional Review Board (IRB) of the Virginia Department of Health (VDH): Guidelines and Procedures for Obtaining Review*, was developed and approved by the Commissioner in January 2001, 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, 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 "exempt 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 2012, the Commissioner appointed Dev Nair, PhD, MPH, Director of the Division of Policy and Evaluation in the Office of Family Health Services, as the chair of the VDH IRB following the resignation of Dr. Diane Helentjaris.

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 2012.

Review Type	Approved	Not Approved
Full Review	2	0
Expedited Review	18	0
Exempt Review	26	0

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

A. Full Board Reviews

Study#: 40156
Title of Study: Promising Practice Research & Evaluation: Virginia Resource Mothers Program
Principal Investigator: Linda Bullock, PhD, RN, FAAN
Date approved: February 6, 2013
Description of Study: The purpose of research is to determine if pregnant teens who received home visits from the Virginia Department of Health’s Resource Mothers Program’s Community Health Workers during their pregnancy and up to one-year post delivery have better outcomes compared to similar pregnant teens who receive an attention control intervention of telephone support provided by the University of Virginia’s School of Nursing for the same time period. Outcomes are measured by decreased parental stress, decreased rate of reported child abuse, decreased rate of low birth weight, decreased rate of rapid repeat pregnancy and improved school retention and completion (if enrolled at time of pregnancy). The study population is pregnant teens 13-19 years of age. All reports will contain aggregated data and no identifying information will be reported.

Study#: 40161
Title of Study: Motivational Interviewing Integrated with Social Network Counseling for Teens
Principal Investigator: Michael Mason, PhD
Date approved: December 14, 2012
Description of Study: This study is to test the feasibility and efficacy of a 20 minute interview that seeks to alter the substance use trajectory among urban adolescent patients in the primary care setting. Patients aged 14 to 18 who are at risk for substance use will be asked to respond to questionnaires regarding their substance use, sexual history, mental health and their social network. All data will be de-identified only subject number and data will only be used for the purpose of the research. Data security includes the establishment of the Data Security Monitoring Board.

B. Expedited Reviews:

Study #: 40145
Title of Study: Medullary Thyroid Carcinoma Surveillance Study:
A Case-Series Registry
Principal Investigator: Gretchen S. Dieck, PhD
Date approved: January 12, 2012
Description of Study: This is a required FDA post-marking study of the diabetes medication made by Novo Nordisk, Liraglutide (known as the brand name VICTOZA) which was approved by the FDA in January 2010 for the treatment of Type II diabetes. The United BioSource Corporation, Inc.(UBC) will monitor multistate cancer registries to determine the annual incidence of reported Medullary Thyroid Cancer. The state cancer registries will provide case data to UBC either via a secure FTP or password protected CD. If consent is obtained, the UBC will reach out via telephone to patients or designated proxy to obtain additional information.

Study #: 40146
Title of Study: Continued Follow-Up of PLCO Participants
Principal Investigator: Kelly J. Yu, PhD, MPH
Date approved: January 12, 2012
Description of Study: This is a follow-up to a Prostate, Lung, Colorectal, Ovarian (PLCO) Cancer Screening Trial study that was initiated in 1993. The goal of the study is to determine if screening will reduce disease specific mortality rates for PLCO. The PLCO extended follow-up will look for factors which may cause many types of cancer and other diseases. The study involves collecting health related information by mailing questionnaires to participants, vital status ascertainment via National Death Index (NDI) searches, and cancer case ascertainment. The study is being conducted by Westat under contract to the National Cancer Institute.

Study #: 40147
Title of Study: Assisted Reproductive Technology & the Risk of
Childhood Cancer
Principal Investigator: Barbara Luke, ScD, MPH
Date approved: January 12, 2012
Description of Study: This multi-state study will compare the incidence of childhood cancer in children conceived through Assisted Reproductive Technology (ART) to that in the general population. The analysis will include comparisons of total childhood cancer incidences as well as comparisons of specific cancer types. The study will examine risk of cancer by ART treatment parameters and underlying cause of infertility.

Study #: 40148
Title of Study: Central Virginia STI Recidivism Risk Factors
Principal Investigator: Jane Emerson, RN
Date approved: February 10, 2012
Description of Study: The purpose of this study is to determine risk factors for recidivism of STIs in the Central Virginia region and to identify target risk groups for

additional intervention in order to reduce STI transmission. The study will analyze existing Virginia Department of Health data including SSuN data and morbidity reports.

Study #: 40149
Title of Study: Early Intervention Services for Children Who Are Deaf or Hard of Hearing
Principal Investigator: Parthenia Dinora, PhD
Date approved: February 10, 2012
Description of Study: This study will ascertain the process parents use in making a decision about early intervention for their children who have hearing loss by identifying system and personal factors that parents consider when making a decision to enroll, not enroll or discontinue enrollment of their infant in early intervention services. In addition the study will also identify the characteristics of the families and children who were not referred to early intervention.

Study #: 40150
Title of Study: 2012 Virginia Statewide Oral Health Needs Assessment of Sentinel Schools
Principal Investigator: R. Lynn Browder, DDS
Date approved: April 3, 2012
Description of Study: This oral health needs assessment will be conducted by the Virginia Department of Health's Dental Health Program in a representative sample of Virginia's public elementary schools that were surveyed originally in 2009. The purpose of the study is to assess children's oral health through an oral health screening. Parents will be provided screening results and information on available resources for any children with existing dental needs. The information will be used in program planning and evaluation. Findings will be shared with local health districts.

Study #: 40151
Title of Study: Preventing Cervical Cancer in Rural Women through Nurse Practitioner Colposcopy Services: Ensuring Patient Safety and Effectiveness
Principal Investigator: Elizabeth Merwin, PhD, RN, FAAN
Date approved: April 6, 2012
Description of Study: This project links research and innovative practice changes by connecting clinicians and researchers at the University of Virginia in order to determine the best way to organize and implement an expansion of clinical responsibilities of nurse practitioners to include colposcopy in far Southwest Virginia. The study will include interviews with agency and program clinical leaders, surveys of nurse practitioners, and the use of an existing clinical data system. The second phase will include enrolling patients receiving colposcopy services provided by nurse practitioners and evaluating their satisfaction with the service.

Study #: 40152
Title of Study: A Study of Rocky Mountain Spotted Fever Diagnosis in Health Districts in Virginia
Principal Investigator: Lisa Ferguson, RN, BSN
Date approved: April 25, 2012
Description of Study: This project will collect additional laboratory and epidemiological data on reported cases of Rocky Mountain Spotted Fever (RMSF) in an attempt to determine if recent increased reporting of the disease is truly a reflection of increased incidence of acute infection from *Rickettsia* group organisms. Interviews with patients in the study areas will assist in the identification of specific risk factors. The findings will allow the Virginia Department of Health to more effectively draw conclusions about the incidence of RMSF.

Study #: 40153
Title of Study: The Women's Interagency HIV Study (WIHS)
Principal Investigator: Mary Young, MD
Date approved: May 31, 2012
Description of Study: The WIHS is a national, longitudinal epidemiological study of the natural history of HIV in adult women, which began in 1993. Virginia Cancer Registry data, as well as other state cancer registry data, will be included in the study in order to identify unreported cases and/or confirm self-reported cases of cancers among the women in this study.

Study #: 40154
Title of Study: Post-Marketing Surveillance of Adverse Effects of a New Treatment Regimen
Principal Investigator: Christine Ho, MD, MPH
Date approved: August 23, 2012
Description of Study: This is a CDC study to determine treatment outcome, drug interactions and adverse effects of the 3HP treatment regimen for latent TB infection. The project will utilize a prospective observational cohort during implementation of 3HP in the Virginia Department of Health's TB Control program. Individuals included within this project will consent to treatment with the 3HP regimen as part of normal client care. Information obtained may lead to revised recommendations regarding the regimen.

Study #: 40155
Title of Study: An Assessment of Continuation Rates of Implanon in a Rural Health District
Principal Investigator: Elizabeth B. Webster, MD
Date approved: September 10, 2012
Description of Study: This study will review Family Planning Clinic patients in the Three Rivers Health District who selected Implanon devices in 2007 to 2009 and are due to be removed during 2010 to 2012 to determine the reasons women do or do not choose to continue usage of the effective long term contraception. The study findings will be shared with the other health districts' family planning clinics.

Study #: 40157
Title of Study: Barriers and Facilitators to Infant Feeding Among Low-Income African-American Women in Richmond City, Virginia
Principal Investigator: Saba Masho, MD, DrPH
Date approved: October 23, 2012
Description of Study: The purpose of the study is to better understand the barriers and facilitators of infant feeding through focus groups with women and their partners who have recent infant feeding experiences and to engage the community in developing strategies to address barriers with the ultimate aim to improve breastfeeding rates. The results of the study will be presented to the Mayor of Richmond, the Mayor's Advisory Board on Breastfeeding and will be presented to a doctoral committee and published in a doctoral dissertation.

Study #: 40158
Title of Study: Camp Lejeune Health Survey
Principal Investigator: Perri Ruckart, MPH
Date approved: October 25, 2012
Description of Study: This study is being conducted by the Agency for Toxic Substance and Disease Registry (ATSDR) to assess whether there is an association between exposure to the contaminated drinking water at Camp Lejeune and cancer and other specified health conditions. The analysis will focus on reported diseases of interest that are confirmed by medical records or cancer registries.

Study #: 40159
Title of Study: Companion Animals as Sentinels of Human Disease: A Community-based Study
Principal Investigator: Francois Elvinger, PhD
Date approved: November 7, 2012
Description of Study: The purpose of this research is to investigate health trends in the pet population in the Lenowisco Health District to determine if pet health can be a predictor of public health issues impacting humans.

Study #: 40160
Title of Study: An Academic-Community Partnership to Address Health Disparities in Infant Mortality
Principal Investigator: Audra Gollenberg, PhD
Date approved: October 16, 2012
Description of Study: The purpose of the study is to identify and address disparities in infant mortality in the Lord Fairfax Health District. The study will use individual and group interview methodologies to gather information on community strengths and weaknesses, community perceptions and resource needs of the community in order to develop a tailored intervention strategy.

Study #: 40162
Title of Study: Human Face Recognition: Pop-out Effects in Infants
Principal Investigator: Krisztina Jakobsen, PhDA
Date approved: January 25, 2013
Description of Study: The purpose of this study is to determine if all primate faces are processed by a human face recognition system, or whether only human faces are processed by this system. The study subjects will be two groups of infants, 4-6 months and 9-11 months from Harrisonburg and surrounding communities.

Study #: 40163
Title of Study: A Pilot of SBIRT for Risking Drinking and Alcohol-Exposed Pregnancy Risk
Principal Investigator: Karen S. Ingersoll, PhD
Date approved: December 5, 2012
Description of Study: The purpose of this study is to determine feasibility, acceptability and benefits of a screening, brief intervention and referral to treatment (SBIRT) intervention for drinking and ineffective contraceptive use in a women's health setting. Results of the study will inform women's health care providers regarding the early identification and treatment of risky alcohol use and provide pilot data for a larger research study. Study participants will be women 18 years or older attending a family planning or STD clinic at the Virginia Department of Health Waynesboro Women's Health Clinic.

Study #: 40164
Title of Study: Diabetes Among Sworn Public Safety Officers; Control, Compliance and Cost
Principal Investigator: Heidi A. Kulberg, MD, MPH
Date approved: December 13, 2012
Description of Study: The purpose of this study is to determine the occurrence, patient compliance and costs of diabetes in sworn public safety officers. The study findings will be presented to the Chesapeake Occupational Health Services Clinic, Eastern Virginia Medical School Health Professions Department and potentially city leaders.

C. Exemption Reviews

Study #: 50112
Title of Study: Smoking Cessation Quality Improvement Project
Principal Investigator: Shaylona Kirk
Date approved: January 12, 2012
Description of Study: This project assesses patient counseling regarding their knowledge of smoking risks through the administration of an anonymous survey.

Study #: 50113
Title of Study: Socio-Demographic Factors Contributing to a Disparate Burden of Second-Hand Smoke Exposure among Nonsmoking Adults in Virginia
Principal Investigator: Carolyn Cokes
Date approved: March 5, 2012
Description of Study: Data from the Virginia sample from the National Adult Tobacco Survey will be analyzed to characterize differences between smoking prevalence and exposure to second-hand smoke based on socio-demographic and socio-economic factors with the purpose of identifying disparities among those exposed to second-hand smoke.

Study #: 50114
Title of Study: Pregnancy Assistance Fund Grant (PAF) Pregnant and Parenting Student Support in Institutions of Higher Education (IHE)
Principal Investigator: Jaimie H. Caleb
Date approved: March 7, 2012
Description of Study: The purpose of this study is to evaluate the Pregnant and Parenting Student Support in Institutions of Higher Education program. The study will document the demographics of the student-parent population served through the program, determine the extent the participating colleges are meeting the programmatic objectives and determine the student-parent satisfaction with the program staff, services, and referrals.

Study #: 50115
Title of Study: The Association between Co-occurring Risk Factors and Pregnancy Intention Among Women in Virginia
Principal Investigator: Selamawit Girma
Date approved: February 28, 2012
Description of Study: The purpose of this study is to provide an increased understanding of the issues involved in unintended pregnancy using de-identified PRAMS data.

Study #: 50116
Title of Study: Alexandria Fire Department Closed Point of Dispensing Exercise 2012: Evaluating First Responder Attitudes toward Medication Dispensed at a Closed Point of Dispensing
Principal Investigator: Stephen A. Haering, MD, MPH
Date approved: March 20, 2012
Description of Study: The purpose of this study is to provide the City of Alexandria with the framework through which local/regional, private and civic organizations can demonstrate preparation and response capabilities surrounding medication dispensing to staff and families.

Study #: 50117
Title of Study: A Descriptive Study of Teen Pregnancy Rates and Associated Modifying Factors in the Commonwealth of Virginia
Principal Investigator: Rhona Collins
Date approved: April 3, 2012
Description of Study: The purpose of this study is identify potential intervention strategies to reduce teen pregnancy rates through an analysis of 2006-2010 Virginia teen pregnancy rates for ages 15 – 19 and the identification of any modifying factors.

Study #: 50118
Title of Study: Alzheimer’s Association BRFSS State Reports on Dementia and Caregiving
Principal Investigator: Elena M. Andresen, PhD
Date approved: March 23, 2012
Description of Study: The purpose of this project is to review the 2010 Behavioral Risk Factor Surveillance System survey (BRFSS) caregiving module data from seven states (Connecticut, New Hampshire, New Jersey, New York, North Carolina, Tennessee, and Virginia) and provide a report that summarizes overall findings of interest among caregivers, the special subgroup of caregivers of persons with Alzheimer’s disease or dementia, and non-caregivers. A separate summary describing general caregiving characteristics will be provided that describes caregiving by other major health conditions, e.g., cancer, cardiovascular disease, arthritis, etc.

Study #: 50119
Title of Study: Survey to Determine Clinician Mammography Referral Patterns
Principal Investigator: Kathleen Rocco
Date approved: April 26, 2012
Description of Study: This study will collect and analyze survey data from Virginia clinicians to determine the mammography referral resources that they use.

Study #: 50120
Title of Study: Evaluation of Hepatitis B Case Reporting in Virginia
Principal Investigator: Margaret A. Tipple, MD
Date approved: April 18, 2012
Description of Study: Existing data from the VEDSS and other DSI reporting systems will be analyzed to determine characteristics of hepatitis B cases and limitations of the VEDSS system. Information will be used for program planning in the VDH Division of Surveillance and Investigation.

Study #: 50121
Title of Study: SOLVE (School-located Vaccination Evaluation) Billing and Claims Study
Principal Investigator: Paige Lucas, MPH, CHES
Date approved: April 25, 2012
Description of Study: This is a Center for Disease Control and Prevention (CDC) Sponsored national study that includes a web-based survey to determine the knowledge,

Attitudes and beliefs about SOLVE among school-level personnel (principals and school Nurses). De-identified data from the survey will be included in the national data base.

Study #: 50122
Title of Study: Assessment for Reproductive Coercion at Domestic Violence Program
Principal Investigator: Laura K. Crawford
Date approved: May 2, 2012
Description of Study: Questions will be added to the intake form for the Project Connect domestic violence project sites in Charlottesville and the Northern Neck to assess the effectiveness of using these questions in identifying reproductive coercion. Data will be collected and provided to VDH in aggregate format.

Study #: 50123
Title of Study: Assessment for Domestic Violence in Home Visiting Settings
Principal Investigator: Laura K. Crawford
Date approved: May 14, 2012
Description of Study: The purpose of this study is to assess the effectiveness of the evidence-based Relationship Assessment tool to identify those experiencing abuse in home visiting settings and to record referrals given to them by home visitors in the Project Connect sites in Charlottesville and the Northern Neck. Aggregate data will be provided to VDH for analysis.

Study #: 50124
Title of Study: Alexandria Community Environmental Health Assessment: Measuring Community Concern Regarding Environmental Health Issues
Principal Investigator: Stephen Haering, MD, MPH
Date approved: May 10, 2012
Description of Study: The purpose of this study is to identify environmental health issues through focus group discussions with residents, environmental science and health professionals.

Study #: 50125
Title of Study: Family Planning Patient SBIRT Survey
Principal Investigator: Jennifer Hetteema, PhD
Date approved: May 17, 2012
Description of Study: The purpose of this study is to assess VDH family planning patients regarding risky alcohol use, contraception behavior, and attitudes toward receiving alcohol focused brief interventions (SBIRT) from family health providers through an anonymous self-administered survey. Study was previously approved by the UVA/IRB.

Study #: 50126
Title of Study: Evaluation of Naegleria Case Reporting in Virginia
Principal Investigator: Jennifer Espiritu, MD, MPH
Date approved: May 30, 2012
Description of Study: The evaluation of the Naegleria case reporting will be conducted by cross-checking death records from the months of May-September with obituaries and newspaper reports to determine any evidence of water exposure.

Study #: 50127
Title of Study: Investigation of the Effects of Fluoride Concentration in Community Water System on the Oral Health of Residents
Principal Investigator: Ji Won Lee
Date approved: May 23, 2012
Description of Study: Student project using Geospatial Analysis (GIS) to analyze oral health and fluoridation levels for Virginia Counties, Jefferson County, WVA and Washington, DC.

Study #: 50128
Title of Study: Investigation of the Relationship Between High School Students' Self-Reports of Suicidality, Sad Feelings and Bullying Behavior
Principal Investigator: Heather Merner, M.A
Date approved: July 11, 2012
Description of Study: This study will use the Youth Risk Behavior Survey (YRBS) data to analyze the relationship between student self-reports of suicidality, sad feelings and bullying behavior.

Study #: 50129
Title of Study: Factors Involved in Young Women's Decision to Use Long-Acting Reversible Contraception in Rural Virginia
Principal Investigator: Sharon Cooley, MSN, CFNP
Date approved: July 11, 2012
Description of Study: Women ages 18 to 30 in Southeastern Virginia family planning clinics will be asked to complete anonymous survey to determine the factors involved in the decision to use a long-lasting reversible contraception method.

Study #: 50130
Title of Study: Evaluation of Salmonellosis and E. Coli Investigation Data
Principal Investigator: Tim Powell, MPH
Date approved: July 19, 2012
Description of Study: This study includes the analysis of the STEC case reports and Salmonellosis case reports to determine completeness, quality, and timeliness of each case report. The study does not involve human subject testing and only involves previously collected de-identified data by the state health department.

Study #: 50131
Title of Study: Geographic Correlates of Lyme Disease Risk in Virginia and North Carolina
Principal Investigator: Paul Lantos, MD
Date approved: July 19, 2012
Description of Study: Statistical/spatial analyses will be used to determine the geographic correlates of Lyme Disease risk in Virginia and North Carolina.

Study #: 50132
Title of Study: Implementation of a Title X Male Reproductive Health Program in Virginia: Challenges from a Public Health Nursing Perspective
Principal Investigator: Barbara Walsh, MPH, RN, PHCNS-BC
Date approved: July 19, 2012
Description of Study: The purpose of this study is to survey public health department nurses to determine the challenges in implementing the Title X Male Reproductive Health Program.

Study #: 50133
Title of Study: Alcohol-Attributable Deaths and Rates by Selected Characteristics, Selected States, US, 2005-2009
Principal Investigator: Danielle Henderson, MPH
Date approved: August 10, 2012
Description of Study: The project involves the analysis of 2005-2009 years of mortality data containing no personal identifiable information. Virginia is included in the study along with a number of other states. The study is supported by the Centers for Disease Control (CDC) Alcohol Program.

Study #: 50134
Title of Study: Critical Congenital Heart Disease Demonstration Project (DDHDDP)
Principal Investigator: Kathleen Moline, MA, BSN
Date approved: September 24, 2012
Description of Study: The Virginia Department of Health, in partnership with an identified network of birth hospitals and workgroup of key stakeholders, will develop, disseminate, and validate screening protocols and create a statewide newborn screening infrastructure to support point of care screening specific to Critical Congenital Heart Disease (CCHD).

Study #: 50135
Title of Study: Using GI Syndrome Data as an Early Warning Tool for Norovirus Outbreak Activity
Principal Investigator: Erin Austin
Date approved: October 16, 2012
Description of Study: The purpose of this study is to assess the relationship between emergency department and urgent care center chief complaint data for gastrointestinal illness and reported Norovirus outbreaks to develop an early warning tool for outbreak activity which can be used to direct public health actions.

Study #: 50136
Title of Study: Virginia Early Childhood Needs Assessment
Principal Investigator: John Almarode, PhD
Date approved: December 5, 2012
Description of Study: The Virginia Pregnancy Risk Assessment Monitoring System (PRAMS) dataset will be used to estimate the number of children 0-5 years old who will be eligible for early childhood education programs and services in the near term (2012-2015).

Study #: 50137
Title of Study: Vote & Vax Virginia 2012
Principal Investigator: Joseph Hoyle
Date approved: November 28, 2012
Description of Study: This evaluation will use interviews of key stakeholders including pharmacists, election officials, health district, area agencies on aging representative and Medical Reserve Corps participants to evaluate the Vote & VAX program.

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 2012		
Committee Members	Qualifications for Service	Institutional Affiliation
IRB CHAIR		
Dev Nair	PhD in Clinical Psychology, MPH in Health Management & Policy. Director of the Division of Policy & Evaluation	Virginia Department of Health
VOTING MEMBERS		
Jeffrey Stover	MPH, Public Health Epidemiology. Director of Health Informatics & Integrated Surveillance Systems	Virginia Department of Health
Ana Lizzette Colon	MPH. in Epidemiology & Regional Surveillance Coordinator	Virginia Department of Health, Eastern Region Field Office
Bethany J. Geldmaker	PhD in Nursing & Child Health Care Consultant	Virginia Department of Health
Ronnette Langhorne	RN, MS, Nurse Manger	Norfolk Virginia Department of Health
Janice Hicks	PhD in Social Policy and Social Work	Virginia Department of Health
J. Elisha Burke	Rev., Dr., and Director, Men's Health and Wellness Ministry	Baptist General Convention of Virginia
ALTERNATE MEMBERS		
Vacant		

**Virginia Department of Health
Institutional Review Board**

Minutes

January 9, 2012

10:30 AM – 12:30 PM

Members Present: Diane Helentjaris, Elisha Burke (arrived @ 10:32), Ana Colon (arrived @10:38),David Trump (arrived @ 10:33), Bethany Geldmaker, Janice Hicks, Tywanda Bolden

Members Absent: Gail Jennings resigned effective January 4, 2012.

General Items/Announcements:

- The meeting was convened at 12:40 AM. A quorum was present.
- Minutes from the October meeting were unanimously approved.
- Seeking suggestions for new IRB members; subject experts would be helpful.
- VDH IRB Meeting dates Year 2012, at 10:30 -12:30

April 2

July 9

October 1

PRESENTATION OF NEW PROTOCOLS – EXEMPTION REVIEW:

Study#:	50105
Title of Study:	A Spatial and Demographic Analysis of Core of Areas Chlamydia Infection in Virginia
Principal Investigator:	Sarah Salino/Carrie Dolan
Primary Reviewer:	Ana Colon
Discussion:	Analyze secondary historical Chlamydia surveillance data as part of the evaluation testing. No interaction with humans or use of patient identifiers.
Description of Action:	Unanimously Approved.
Study#:	50106
Title of Study:	Development of Alternate Methods of Disseminating Information Providing Prophylaxis to Minority population during Mass Prophylaxis scenario
Principal Investigator:	Kevin Culbert
Primary Reviewer:	Gail Jennings
Discussion:	Frederick County data used.
Description of Action:	Unanimously Approved.

Study#: 50107
Title of Study: BRFSS Analysis for Virginia Health Promotion for People with Disabilities (HPPD) Project
Principal Investigator: Donna Gilles
Primary Reviewer: Bethany Geldmaker
Discussion: Telephone survey; publication.
Description of Action: Unanimously Approved.

Study#: 50108
Title of Study: Environmental Variability and Disease Emergence: Spatial Patterns of Lyme Disease Emergence in Virginia
Principal Investigator: Korine Kollivaris, PhD
Primary Reviewer: Bethany Geldmaker
Discussion: Patterns of Lyme Disease description, mapping and imaging.
Description of Action: Unanimously Approved.

Study#: 50109
Title of Study: Intergenerational Risk Factors
Principal Investigator: Derek A. Chapman, PhD
Primary Reviewer: David Trump
Discussion: Question if VDH internal or external study ; funding and publication questions.
Description of Action: Study remains open for discussion.

Study#: 50110
Title of Study: Parental characteristics of teen births resulting from sex with an older partner, 2000-2009
Principal Investigator: Gandarvaka Gray
Primary Reviewer: Elisha Burke
Discussion: Using pre-existing data.
Description of Action: Unanimously Approved.

Study#: 50111
Title of Study: Behavioral Risk Factor Surveillance System (BRFSS)
Principal Investigator : Susan Kennedy Spain
Primary Reviewer: Reviewed at the January 9, 2012 meeting.
Discussion: Need to determine if the income level has been modified.
Description of Action: Unanimously approved pending clarification on income variable.

PRESENTATION OF NEW PROTOCOLS – EXPEDITED REVIEW:

Study#: 40138
Title of Study: Children’s Understanding of Arrows
Principal Investigator: Krisztina Varga Jakobsen, PhD
Primary Reviewer: Elisha Burke
Discussion: None.

Description of Action: Unanimously Approved.

Study#: 40139
Title of Study: Garrett Lee Smith Suicide Prevention Program Evaluation
Principal Investigator: Stephanie Goodman, MPH
Primary Reviewer: David Trump
Discussion: None.
Description of Action: Unanimously Approved.

Study#: 40140
Title of Study: Lord Fairfax Health Department Youth Behavior Survey
Principal Investigator: Charles Devine, Md
Primary Reviewer: Bethany Geldmaker
Discussion: Ownership of the results –Department of Education or Virginia Department of Health; security issues on answered forms.
Description of Action: Unanimously Approved.

Study#: 40141
Title of Study: Response Program Evaluation
Principal Investigator: Stephanie Goodman, PhD
Primary Reviewer: David Trump
Discussion: Flag this study as a good example of the protocols; no other IRB reviewing this study.
Description of Action: Unanimously Approved.

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
Primary Reviewer: Gail Jennings
Discussion: Separate forms for female and male participants that are gender specific in use of pronouns; researchers given explicit instructions to participants on how to read and complete the form.
Description of Action: Unanimously Approved.

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
Primary Reviewer: Ana Colon
Discussion: No minor child will be participating in this survey, change authorized signature to participant signature; what questions will be asked during the follow-up phone interview.
Description of Action: Unanimously Approved.

Study#: 40144
Title of Study: Project Connect: Evaluation of Public Health Partnership to Prevent Violence Against Women
Principal Investigator: Elizabeth Miller, MD, PhD
Primary Reviewer: Bethany Geldmaker
Discussion: Multi-state project (federal funds).
Description of Action: Unanimously Approved.

Study#: 40145
Title of Study: Medullary Thyroid Carcinoma Surveillance Study: a Case- Series Registry
Principal Investigator: Gretchen S. Dieck, PhD
Primary Review: Ana Colon
Discussion: Pre-clinical studies approved –FDA now doing post-marketing study as required.
Description of Action: Unanimously Approved.

Study #: 40146
Title of Study: Continued Follow-Up of PLCO Participants
Principal Investigator: Kelly J Yu, PhD
Primary Reviewer: Bethany Geldmaker
Discussion: Study will run from 2012-2016.
Description of Action: Unanimously Approved.

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, PhD, MPH
Discussion: 291 participants were submitted; PI provided information regarding recent publications.
Description of Action: Unanimously Approved.

Study#: 40032
Title of Study: Interview of Person from which Enteric Bacterial Isolates have been Cultured with Uncommon Antimicrobial Resistance Patterns
Principal Investigator: Regan Ricket
Discussion: 108 subjects entered in the study; several publication surrounding the research.
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: Twenty-seven subjects enrolled; ten deceased enrolled for medical record and nineteen health districts interviewed; working on data cleanup issues. August 31, 2010 an interview booklet, informed consent form and receipt for the gift card incentive was lost. Information could be lost, stolen or accidentally released; exhausted all possible means of recovering documents.

Study #: 40114
Title of Study: Virginia Youth Survey
Principal Investigator: Shanee Harmon
Discussion: None.
Description of Action: Unanimously Approved.

Study#: 40121
Title of Study: An Art-Based Psychoeducational Group for Pregnant Teenagers
Principal Investigator: Laura S Maloney, ATR-BC, LPC, LMFT
Discussion: Summary provided.
Description of Action: Study completed and closed.

Study#: 40122
Title of Study: Evaluation of Academic Performance of Hampton Healthy Start Graduates
Principal Investigator: Jerrica Nichols, MPH
Discussion: Summary provided.
Description of Action: Study completed and closed.

Study#: 40123
Title of Study: Evaluation of Host Immune Responses to Hepatitis B Vaccine B Among Patients Vaccinated in Response to Hepatitis B Outbreak Investigation
Principal Investigator: Thomas John Bender, MD, PhD
Discussion: Summary provided.
Description of Action: Study completed and closed.

Study#: 40124
Title of Study: Latinas' Contraception Experience and Planning (LCEP)
Principal Investigator: Jacqueline M. McGrath, PhD, RN, FNAP,FAAN
Discussion: Summary provided.
Description of Action: Study closed but waiting on final interview analysis.

Study#: 40125
Title of Study: The Vaginal Microbiome: Disease, Genetics and the Environment
Principal Investigator: Gregory Buck, PhD
Discussion: Summary provided.
Description of Action: Unanimously Approved.

OTHER (MINOR MODIFICATIONS, ETC):

Study#: 40069
Title of Study: Virginia Pregnancy Risk Assessment Monitoring System (VA-PRAMS)
Type of Review: Minor Modification
Description: Revised questions combining H1N1 and seasonal vaccines; elimination of questions regarding reasons why mothers did not get a flu shot; and inclusion of questions regarding Tdap, emergency preparedness, physical activity and infant car seat(in both English and Spanish).
Discussion: None.
Description of Action: Unanimously Approved.

Study#: 40110
Title of Study: Improving the Management of Tuberculosis in Patients from Virginia Using the Whole-Blood Bactericidal Assay
Type of Review: Minor Modification
Description: The recruitment letter will be given to doctors and nurses of the patients who are referred to tuberculosis State Department clinic, they will speak to patients about this study.
Discussion: None.
Description of Action: Unanimously Approved.

Study#: 40144
Title of Study: Project Connect: Evaluation of a Public Health Partnership to Prevent Violence Against Women
Type of Review: Minor Modification
Discussion: Principal Investigator has changed
Discussion: None
Description of Action: Unanimously Approved

Meeting adjourned @12:40.

**Virginia Department of Health
Institutional Review Board**

MINUTES
April 2, 2012

Members Present: Elisha Burke, David Trump, Diane Helentjaris (arrived @ 10:34), Ana Colon (arrived @ 10:36).

Staff Present: Janice Hicks, Tywanda Bolden

Members Absent: Bethany Geldmaker

Guests: Dev Nair, Ph.D

General Items/Announcement:

- The meeting was convened at 10:30 AM. A quorum was present.
- Minutes from January meeting were unanimously approved.
- New Chair proposed to Commissioner
 - Dev Nair, PhD., Director of Policy & Evaluation
- New Member Proposed to Commissioner
 - Jeffrey Stover, Director of Health Informatics & Integrated Surveillance System
- Discussion of possible new members
 - Gordon Green
 - A District Nurse Manager/District Director
 - Office of Information Management employee
- Discussion of available agency guidelines regarding data security
- Discussion of need for a standardized review form
- VDH IRB Meeting remaining meeting dates for 2012

July 9

October 1

PRESENTATION OF NEW PROTOCOLS – EXEMPTION REVIEW:

Study #:	50109
Title of Study:	Intergeneration Risk Factors
Principal Investigator:	Derek Chapman, PhD
Primary Reviewer:	David Trump
Discussion:	Using existing dataset created by VDH Office of Family Health Services linked to Vital Records birth data. Dataset has been coded so that subjects cannot be identified directly.

Description of Action: Unanimously Approved.

Study#: 50112
Title of Study: Smoking Cessation Quality Improvement Project
Principal Investigator: Shaylona Kirk
Primary Reviewer: Bethany Geldmaker
Discussion: Counseling to patients about the knowledge base about the risks of smoking. Information will be assessed using a survey questionnaire which patients can answer anonymously.

Description of Action: Unanimously Approved.

Study#: 50113
Title of Study: Socio-demographic factors contributing to a Disparate burden of Second-hand smoke exposure among nonsmoking adults in Virginia
Principal Investigator: Carolyn Cokes
Primary Reviewer: David Trump
Discussion: Research involves study of existing data; information is recorded in such a manner that the subjects cannot be identified directly.

Description of Action: Unanimously Approved.

Study#: 50114
Title of Study: Pregnancy Assistance Fund Grant (PAF) Pregnant and Parenting Student Support in Institutions of Higher Education (IHE)
Principal Investigator: Jaimie H. Caleb
Primary Reviewer: Elisha Burke
Discussion: Reporting for a grant; student-parent male or female currently pregnant, expecting or parenting a child 5 yrs. old receiving assistance; survey online.

Description of Action: Unanimously Approved.

Study#: 50115
Title of Study: The Association between Co-occurring Risk Factors and Pregnancy Intention Among Women in Virginia
Principal Investigator: Selamawit Girma
Primary Reviewer: Bethany Geldmaker
Discussion: Interesting student project; to better understand the issues behind unintended pregnancy. Cross sectional analysis of three years of Virginia PRAMS data; de-identified.

Description of Action: Unanimously Approved.

Study#: 50116
Title of Study: Alexandria Fire Department Closed Point of Dispensing

Principal Investigator: Exercise 2012: Evaluating first responder attitudes toward medication dispensed at a closed point of dispensing
Primary Reviewer: Stephen A. Haering, MD, MPH
Discussion: Bethany Geldmaker
To provide the City of Alexandria with the framework through which local/regional, private and civic organizations can demonstrate preparation and response capabilities surrounding medication dispensing ; provide prophylaxis to staff and families.
Description of Action: Unanimously Approved.

Study#: 50117
Title of Study: A Description Study of Teen Pregnancy Rates and Associated Modifying Factors in the Commonwealth of Virginia

Principal Investigator: Rhona Collins
Primary Reviewer: Elisha Burke
Discussion: Teen pregnancy rate in Virginia 2006-2010 and ages 15-19; existing data provided; working on intervention strategies to reduce teen pregnancy rate.
Description of Action: Unanimously Approved.

Study#: 50118
Title of Study: Alzheimer's Association BRFSS State Reports on Dementia and Caregiving
Principal Investigator: Elena M. Andresen, PhD
Primary Reviewer: David Trump
Discussion: Principal Investigator is faculty from the University of Oregon; existing Virginia BRFSS data used and data from other states.
Description of Action: Unanimously Approved.

PRESENTATION OF NEW PROTOCOLS – EXPEDITED REVIEW:

Study#: 40147
Title of Study: Assisted Reproductive Technology & the Risk of Childhood Cancer
Principal Investigator: Barbara Like, ScD, MPH
Primary Reviewer: Bethany Geldmaker
Discussion: To compare childhood cancer in children from the same pregnancy or different pregnancies; Michigan State University and University of Minnesota IRB reviewing this project; the study require a three-way linkage of data.
Description of Action: Unanimously Approved.

Study#: 40148

Title of Study: Central Virginia STI Recidivism Risk Factors
Principal Investigator: Jane Emerson, RN
Primary Reviewer: Ana Colon
Discussion: The principal investigator is a VDH staff conducting an analysis of existent data where identifiers are not used; the geospatial analysis will be done at the county level.
Description of Action: Unanimously Approved.

Study#: 40149
Title of Study: Early Intervention Services for Children who are Deaf or Hard of Hearing
Principal Investigator: Parthenia Dinora, PhD
Primary Reviewer: Bethany Geldmaker
Discussion: Interviews will be conducted in English and Spanish; Reviewer discussed with the PI the limitations of only having the interviews in English and Spanish. PI understands the issues related to language; however budget is limited.
Description of Action: Unanimously Approved.

Study#: 40150
Title of Study: 2012 Virginia Statewide Oral Health Needs Assessments of Sentinel Schools
Principal Investigator: R. Lynn Browder, DDS
Primary Reviewer: Ana Colon
Discussion: Will finding be shared with the parents? The parents do receive a report. Children with urgent dental needs will receive referrals to dental providers. This is a follow-up of children identified in the 2009 3rd grader assessment written; finding will be shared with local health districts.
Description of Action: Unanimously Approved.

PRESENTATION OF NEW PROTOCOLS – FULL BOARD REVIEW:

None.

CONTINUATION REVIEWS/RENEWALS:

Study#: 40016
Title of Study: Early Family Centered Prevention of Conduct and Drug Use in Rural Population
Principal Investigator: Melvin N. Wilson, 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, MD, MPH

Discussion: None

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: Karen C. Day

Discussion: The current principal investigator has retired. The replacement will be Susan H. Pharr (CV enclosed in File)

Description of Action: Unanimously Approved.

Study#: 40098

Title of Study: Invasive MRSA in South Hampton Virginia

Principal Investigator: Batrina Martin, PhD

Discussion: Closed due to non-compliance with the federal regulations

Description of Action: Unanimously Approved.

Study#: 40105

Title of Study: Virginia Comprehensive Cancer Control Project

Principal Investigator: Jean Gaare Eby, ScD

Discussion: None

Description of Action: Unanimously Approved.

Study#: 40106

Title of Study: Forteo Patient Registry

Principal Investigator: Alicia Gilseman, PhD

Discussion: It was noted that adverse events were reported regarding the accidental disclosures of patient information. A request was made for a copy of info sent to the RTI IRB regarding the report and the actions taken to minimize future occurrences. Janice Hicks sent an email to PI requesting info on April 3rd. Response provided on April 11, 2012 and is in the file.

Description of Action: Unanimously Approved.

Study#: 40107

Title of Study:	Baby Basic Mom 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
Title of Study:	Prenatal Education Video Study
Principal Investigator:	Ann L. Kellams, MD, IBCLC, FAAP
Discussion:	None
Description of Action:	Unanimously Approved.
Study#:	40126
Title of Study:	WIC Program Assessment
Principal Investigator:	Mary Beth Dunkerberger
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
Discussion:	Summary provided.
Description of Action:	Study closed but waiting on final analysis of the project.
Study#:	40128
Title of Study:	Guided Imagery Effects on Pregnancy Symptoms and Outcomes
Principal Investigator:	Nancy Jallo, PhD, RNC, FNP-BC, CNS
Discussion:	None
Description of Action;	Unanimously Approved.
Study#:	40129
Title of Study:	Analysis of Animal Exposure in South East Virginia
Principal Investigator:	Hind Baydoun, PhD
Discussion:	Summary provided.
Description of Action:	Study completed and closed.
Study#:	40131
Title of Study:	Project Connect: Evaluation of a Public Health Partnership to Prevent Violence Against Women

Principal Investigator: Elizabeth Miller
Discussion: Summary provided.
Description of Action: Study completed and closed.

Study#: 40132
Title of Study: Smoking Cessation during Pregnancy
Principal Investigator: Linda Bullock, PhD, RN, FAAN
Discussion: None
Description of Action: Unanimously Approved.

OTHER : (MINOR MODIFICATIONS, ETC);

Study#: 40076
Title of Study: Black Women's Health Study: A Follow-Up Study
Principal Investigator: Lynn Rosenberg, Sc.D
Type of Review: Minor Modification
Description: The plan is to request cancer registry data on Black Women's Health Study (BWHS) participants who are lost to follow-up if they have completed a questionnaire that was accompanied by a letter stating that cancer registry data would be obtained.
Discussion: None.
Description of Action: Unanimously Approved.

Study#: 40109
Title of Study: Prenatal Education Video Study
Principal Investigator: Ann L. Kellam, MD, IBCLC, FAAP
Type of Review: Minor Modification
Description: The delivery medical record abstraction; the mother's record will be reviewed and maternal pre-pregnancy weight, height and/ or body mass index (BMI) will recorded. The consent form includes additional information concerning contact information; the study team may use text or email messaging to reach subjects that cannot be reached by phone.
Discussion: None
Description of Action: Unanimously Approved.

VDH IRB Meeting adjourned at 12:40 PM.

**VIRGINIA DEPARTMENT OF HEALTH
INSTITUTIONAL REVIEW BOARD
MINUTES
JULY 9, 2012**

Members Present: Chair Dev Nair, Elisha Burke, Bethany Geldmaker (arrived @ 10:32), Ana Colon (arrived @ 10:34), and Jeffrey Stover

Guests: Ronnette Langhorne, Registered Nurse Manager, Norfolk Health District

Staff Present: Janice Hicks, Tywanda Bolden

General Items/Announcements:

- The meeting was convened at 10:35 AM. A quorum was present.
- Minutes from the April meeting were unanimously approved.
- VDH/IRB website has been updated.
- Draft Review Form was considered and approved.
- Members noted the need to have the faculty advisor identified on all student research IRB requests.
- Reminder – CITI training is required for all members. Completed training certificates are kept on file.
- Policy and procedures are being reviewed and updated.
- Discussion of potential new members – a district director and a non-scientific community member.
- IRB meeting dates for remainder of 2012 and 2013:
 - **October 1, 2012**
 - **January 7, 2013**
 - **April 8, 2013**
 - **July 8, 2013**
 - **October 7, 2013**

PRESENTATION OF NEW PROTOCOLS –EXEMPTION REVIEW:

Study#:	50119
Title of Study:	Survey to Determine Clinician Mammography Referral Patterns
Principal Investigator:	Kathleen Rocco
Primary Reviewer:	Elisha Burke
Discussion:	The survey will be emailed to clinician across the state; no patient information; twelve questions.

Description of Action: Unanimously Approved

Study#: 50120
Title of Study: Evaluation of Hepatitis B Case Reporting in Virginia
Principal Investigator: Margaret A. Tipple, MD
Primary Reviewer: Bethany Geldmaker
Discussion: Analysis of existing data from the VEDSS and other DSI reporting systems to determine characteristics of hepatitis B cases and limitations of the VEDSS system. Information will be used for program planning in the VDH Division of Surveillance and Investigation.

Description of Action: Unanimously Approved

Study#: 50121
Title of Study: SOLVE (School-located Vaccination Evaluation) Billing and Claims Study
Principal Investigator: Paige Lucas, MPH, CHES
Primary Reviewer: Bethany Geldmaker
Discussion: This is a Center for Disease Control Prevention sponsored national study; a web-based survey to determine the knowledge, attitudes and beliefs about SOLVE among school-level personnel (principals and school nurses). De-identified data from the survey will be added to the national data base.

Description of Action: Unanimously Approved

Study#: 50122
Title of Study: Assessment for Reproductive Coercion at Domestic Violence Program
Principal Investigator: Laura K. Crawford
Primary Reviewer: Bethany Geldmaker
Discussion: Adding questions regarding reproductive coercion to the intake form for the Project Connect domestic violence sites in Charlottesville and Northern Neck to assess the effectiveness of using these questions in identifying coercion. Data will be collected and provided to VDH in aggregate format.

Description of Action: Unanimously Approved

Study#: 50123
Title of Study: Assessment for Domestic Violence in Home Visiting Settings
Principal Investigator: Laura K. Crawford
Primary Reviewer: Bethany Geldmaker
Discussion: Study is to assess the effectiveness of the evidence-based Relationship Assessment tool to identify those experiencing

abuse in home visiting settings and to record referrals given to them by home visitors in the Project Connect sites in Charlottesville and the Northern Neck. Aggregate data will be provided to VDH for analysis.

Description of Action:

Unanimously Approved

Study#:

50124

Title of Study:

Alexandria Community Environmental Health Assessment: Measuring Community Concern Regarding Environmental Health Issues

Principal Investigator:

Stephen Haering, MD, MPH

Primary Reviewer:

Elisha Burke

Discussion:

Focus group discussions with residents, environmental science, policy and health professionals; invited through email or telephone; lasting no longer than two hours; informal consent verbally; participants will not be paid nor receive compensation for their time.

Description of Action:

Unanimously Approved

Study#:

50125

Title of Study:

Family Planning Patient SBIRT Survey

Principal Investigator:

Jennifer Hetteema, Ph.D

Primary Reviewer:

Ana Colon

Discussion:

Anonymous self-administered survey of VDH family planning patients regarding risky alcohol use, contraception behavior, and attitudes toward receiving alcohol focused brief interventions from family health providers. Approved by UVA/IRB on April 17, 2012.

Description of Action:

Unanimously Approved

Study#:

50126

Title of Study:

Evaluation of Naegleria Case Reporting in Virginia

Principal Investigator:

Jennifer Espiritu, MD, MPH

Primary Reviewer:

Ana Colon

Discussion:

Names on one hundred and twenty-four death records in the months of May-September will be crosschecked with obituaries and newspaper reports to determine evidence of water exposure.

Description of Action:

Unanimously Approved

Study#:

50127

Title of Study:

Investigation of the Effects of Fluoride Concentration in Community Water System on the Oral Health of Residents

Principal Investigator:

Ji Won Lee (student)

Primary Reviewer: Bethany Geldmaker
Discussion: Student project using Geospatial Analysis (GIS) to analyze oral health and fluoridation levels for Virginia Counties, Jefferson County, WVA and Washington, DC.
Description of Action: Unanimously Approved

PRESENTATION OF NEW PROTOCOLS – EXPEDITED REVIEWS:

Study#: 40151
Title of Study: Preventing Cervical Cancer in Rural Women through Nurse Practitioner Colposcopy Services: Ensuring Patient Safety and Effectiveness
Principal Investigator: Elizabeth Merwin, Ph.D, RN, FAAN
Primary Reviewer: Bethany Geldmaker
Discussion: An evaluation of the impact of the Videocolposcopy Program. Study includes interview with nurse practitioners, clinical leaders, agency personnel and database managers for the Every Woman’s Life program, analysis of existing data, medical record reviews, surveys/interviews with patients and analysis of trends in mortality and morbidity. Consent and data confidentiality are adequately addressed. Study previously approved by UVA’s Institutional Review Board.
Description of Action: Unanimously Approved

Study#: 40152
Title of Study: A Study of Rocky Mountain Spotted Fever Diagnosed in Select Health Districts in Virginia
Principal Investigator: Lisa Ferguson, RN, BSN
Primary Reviewer: Ana Colon
Discussion: The study is to determine if recent increased reporting of the disease is truly a reflection of increased incidence of acute infection from *Rickettsia* group organisms. Analysis of convalescent samples obtained from patients in the study areas, along with the identification of specific risk factors obtained through patient interviews, will allow the Virginia Department of Health (VDH) to more effectively draw conclusions about RMSF disease incidence statewide. Study is minimal risk and includes informed consent and secure storage of data.
Description of Action: Unanimously Approved

Study#: 40153
Title of Study: The Women’s Interagency HIV Study (WIHS)
Principal Investigator: Mary Young, MD

Primary Reviewer: Elisha Burke
Discussion: Ongoing longitudinal study since 1993; Georgetown University IRB approved. Existing data from the VA Cancer Registry will be recorded in a manner that cannot be identified and will be used to determine the frequency of reported cancer among the women in the study. Data security measures in place. IRB members requested information on any current findings from study.
Description of Action: Unanimously Approved

PRESENTATION OF NEW PROTOCOLS- FULL BOARD REVIEW:
NONE

CONTINUATION REVIEWS/RENEWALS:

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

Study#: 40040
Title of Study: Cohort Cancer Registry Follow-up Study
Principal Investigator: Meir J. Stampfer, MD, Dr.PH
Discussion: None
Description of Action: Unanimously Approved

Study#: 40052
Title of Study: Follow Up Study for Cancer Incidence for the Southern Community Cohort Study (SCCS)
Principal Investigator: William J. Blott, Ph.D.
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, Ph.D
Discussion: None
Description of Action: Unanimously Approved

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

Study#:	40092
Title of Study:	Flight Attendants Health Study: The Incidence of Breast and Other Cancer Among Female Flights Attendants
Principal Investigator:	Lynne Pinkerton, MD, MPH
Discussion:	Data security – IRB members noted that the project uses Iron key flash drive for security.
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, MA
Discussion:	None
Description of Action:	Study complete and 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#:	40130
Title of Study:	Program for Child to Adult Transition of Sickle Cell Care
Principal Investigator:	Wally R. Smith, MD
Discussion:	None
Description of Action:	Unanimously Approved
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
Discussion:	None
Description of Action:	Unanimously Approved
Study#:	40134
Title of Study:	Linkage of Virginia Cancer Registry for an Ongoing Retrospective Study of Satellite Workers
Principal Investigator:	Joseph K. McLaughlin, Ph.D
Discussion:	None
Description of Action:	Unanimously Approved
Study#:	40143
Title of Study:	Knowledge of HPV in Relationship to Acceptance and Barriers of HPV Vaccination

Principal Investigator: Jessica Sharp, Ph.D, PNP-BC, CRNA
Discussion: None
Description of Action: Study completed and closed.

OTHER (MINOR MODIFICATIONS, ETC):

Study#: 40069
Title of Study: Virginia Pregnancy Risk Assessment Monitoring System (VA PRAMS)
Principal Investigator: Derek Chapman, Ph.D
Description: The request to conduct a modified protocol using Pregnancy Risk Assessment Monitoring System (PRAMS) is necessary to reflect changes in the manner PRAMS data is managed and submitted to Center for Disease Control (CDC). These modifications have been approved by CDC Institutional Review board (IRB), they do not affect the risk and benefits of the study; nor do they change the specific aims or design of the study. In June 2012, all PRAMS states will begin using a single system that will simplify the data management and batch submission process. The new system is called PRAMS Integrated Data System (PIDS). The questionnaire has also been updated to include flu questions and additional questions selected with input from stakeholders from a list of optional questions approved by the CDC.
Discussion: None
Description of Action: Unanimously Approved

Study#: 40107
Title of Study: Baby Basics Moms Club
Principal Investigator: Merry McKenna
Description: All sites listed in the study have the opportunity to give a gift card to moms that attend the six core topics; she must be a minimum of six week post partum to participate in the evaluation. The group facilitator will do a face to face questionnaire and a gift care will be presented for their participation. No personal information will be kept only a tally sheet for gift cards given out.
Discussion: None
Description of Action: Unanimously Approved

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
Description: Changes to allow the PI/Coordinator to consent the subject

over the phone, with or without the use of the cryacom. Changes to allow the use of a “short form” for consent for Spanish speaking people and changes on how left over specimens are utilized.

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 R. Smith, MD

Description:

The partial waiver of authorization for recruitment, changes in the informal consent/assent forms.

Discussion:

None

Description of Action:

Unanimously Approved

Study#:

50089

Title of Study:

Rural Psychology Training Models: Compendium of Best Practices and Analysis of Gaps and Barriers to their Widespread Adoption

Principal Investigator:

Janet L. McDaniel, Ph.D

Description:

Extending the study through May 31, 2013 to collect data, analyze results and make recommendations. A survey of members of the Council of University Directors of Clinical Psychology (CUDCP) will be added.

Discussion:

None

Description of Action:

Unanimously Approved

Study#:

50116

Title of Study:

Alexandria Fire Department Closed Point of Dispensing Exercise 2012: Evaluating First Responder Attitudes toward Medication Dispensed at a Closed Point of Dispensing

Principal Investigator:

Stephen A. Haering, MD, MPH

Description:

The date of the exercise has changed from March 28, 2012 to June 6, 2012; the survey has some minor editing of phrases for clarification.

Discussion:

None

Description of Action:

Unanimously Approved

VDH IRB MEETING ADJOURNED AT 12:47 PM.

**VIRGINIA DEPARTMENT OF HEALTH
INSTITUTIONAL REVIEW BOARD
MINUTES
OCTOBER 1, 2012**

Members Present: Chair Dev Nair (arrived @ 10:33) Elisha Burke, Jeffrey Stover, Bethany Geldmaker(arrived @ 10:33) Ronnette Langhorne (arrived @ 10:35) Ana Colon (arrived @ 10:40)

Staff Present: Janice Hicks, Tywanda Bolden

General Items/Announcements:

- Full Board Review, October 24, 2012
- Elisha Burke plans to resign after January 7, 2013 meeting.
- Janice Hicks is working on Adverse Event Reporting form.
- Draft IRB Policy provided for member review and feedback
- Suggestion for new members with the committee
 - nonscientific
 - scientific
 - community/ faith based
 - attorney
- VDH IRB Meeting Dates for Year **2013**
 - January 7**
 - **April 8**
 - July 8**
 - October 7**

PRESENTATION OF NEW PROTOCOLS- EXEMPTION REVIEW:

Study#:	50128
Title of Study:	Investigation of the Relationship Between High School Students' Self-Reports of Suicidality, Sad Feelings and Bullying Behavior
Principal Investigator:	Heather Merner, M.A
Primary Reviewer:	Bethany Geldmaker
Discussion:	Study uses a secondary database consisting of survey responses from grades nine through 12; data will not contain any personal identifiers and all study data will be destroyed by the PI once the analysis is completed. The information is important to know in order to help future students who demonstrate signs of mental health problems.
Description of Action:	Unanimously Approved
Study#:	50129

Title of Study: Factors Involved in Young Women’s Decision to Use Long-Acting Reversible Contraception in Rural Virginia

Principal Investigator: Sharon Cooley, MSN, CFNP

Primary Reviewer: Bethany Geldmaker

Discussion: Women ages 18 to 30 in Southeastern Virginia will be surveyed; no identifiable information will be collected. Surveys will be collected in a locked box; data will be analyzed using SPSS software.

Description of Action: Unanimously Approved

Study#: 50130

Title of Study: Evaluation of Salmonellosis and E. Coli Investigation Data

Principal Investigator: Tim Powell, MPH

Primary Reviewer: Elisha Burke

Discussion: Study does not involve human subject testing, only previously collected data by state health departments; all personal identifiers will be removed. Data will be analyzed using Microsoft Access and SAS software.

Description of Action: Unanimously Approved

Study#: 50131

Title of Study: Geographic Correlates of Lyme Disease Risk in Virginia and North Carolina

Principal Investigator: Paul Lantos, MD

Primary Reviewer: Ana Colon

Discussion: Performed at Duke University using geographic information systems (GIS); all information pertaining to human case surveillance will be kept in a secure manner on protected network drives; will include statistical/spatial analyses.

Description of Action: Unanimously Approved

Study#: 50132

Title of Study: Implementation of a Title X Male Reproductive Health Program in Virginia: Challenges from a Public Health Nursing Perspective

Principal Investigator: Barbara Walsh, MPH, RN, PHCNS-BC

Primary Reviewer: Ana Colon

Discussion: Survey of public health department nurses to determine challenges implementing the Title X Male Reproductive Health Program. Data will be entered into a password protected database.

Description of Action: Unanimously Approved

Study#: 50133

Title of Study: Alcohol-Attributable Deaths and Rates by Selected Characteristics, Selected States, US, 2005-2009
Principal Investigator: Danielle Henderson, MPH
Primary Reviewer: Elisha Burke
Discussion: The project involves the analysis of 2005-2009 years of mortality data containing no personal identifiable information. Virginia is included in the study along with a number of other states. The study is supported by the Centers for Disease Control Alcohol Program. The analysis will be included in a Spring 2013 publication.
Description of Action: Unanimously Approved.

Study#: 50134
Title of Study: Critical Congenital Heart Disease Demonstration Project (DDHDDP)
Principal Investigator: Kathleen Moline, MA, BSN
Primary Reviewer: Bethany Geldmaker
Discussion: No more than minimal risk to human subjects; information will be de-identified prior to submission to the Virginia Department of Health (VDH); hospitals will submit data identified by the medical record number; three year grant awarded to implement screening newborns for critical congenital heart disease (CCHD); reporting screening results directly to the Virginia Infant Screening and Infant Tracking System (VISITS) web-based system.
Description of Action: The IRB Chair, Dr. Nair, indicated that as the Policy and Evaluation Division Director he has a conflict of interest in this project. The remaining members unanimously approved the project.

PRESENTATION OF NEW PROTOCOLS-EXPEDITED REVIEWS:

Study#: 40154
Title of Study: Post-Marketing Surveillance of Adverse Effects of a New Treatment Regimen
Principal Investigator: Christine Ho, MD, MPH
Primary Reviewer: Ana Colon
Discussion: The VDH-TB Control Project will be participating in the Centers for Disease Control and Prevention's (CDC) 3HP Post-marketing Surveillance Project. The project will utilize a prospective observational cohort during implementation to carry out surveillance for adverse effects, drug interactions, and/or potential toxicity of the recommended treatment regimen for latent TB infection (LTBI). Data requirements for this project are part of routine client care and documentation during regular

be encounters. Local health departments will fax records to the VDH central office where individual identifying information will be removed. A separate log with client name and study number will be maintained in a locked cabinet in a locked office.

Description of Action: Unanimously Approved

Study#: 40155

Title of Study: An Assessment of Continuation Rates of Implanon in a Rural Health District

Principal Investigator: Elizabeth Belt Webster, MD

Primary Reviewer: Bethany Geldmaker

Discussion: Three Rivers Health District of Virginia Department of Health will review patients selecting Implanon devices between 2007 and 2009 and will contact those who have not continued with use and follow-up to determine reasons for not continuing. The risks have already been taken by the patients when they chose Implanon; informed consent was obtained at that time. The findings will provide for program improvement and potential journal publication.

Description of Action: Unanimously Approved

Study#: 40156

Title of Study: Promising Practice Research and Evaluation: Virginia Resource Mothers Program

Principal Investigator: Linda Bullock, PhD, RN, FAAN

Primary Reviewer: Ronnette Langhorne

Discussion: The members had questions regarding how the new VDH Minor's Confidentiality Policy would impact this project. They agreed that a full discussion with clarification regarding the policy is in order.

Description of Action: Unanimously referred for a full board review

CONTINUATION REVIEWS/RENEWALS:

Study#: 40068

Title of Study: Medical Monitoring Project

Principal Investigator: Dena Benson, MPH

Discussion: None

Description of Action: Unanimously Approved

Study#: 40069

Title of Study: Virginia Pregnancy Risk Assessment Monitoring System (VA-PRAMS)

Principal Investigator: Derek Chapman, PhD

Discussion: The IRB Chair, Dr. Nair, indicated that as the Policy and

Evaluation Division Director he has a conflict of interest in this project. The remaining members unanimously to approve the continuation of this project.

Description of Action: Unanimously Approved

Study#: 40083

Title of Study: See Ya Later Flu-A-Gator: A Childhood Influenza Vaccination Project

Principal Investigator: John Dreyzehner, MD, MPH, FACOEM

Discussion: Principal Investigator is no longer health district director; school-based flu vaccination has grown into a routine service provided by the health department.

Description of Action: Study complete and closed

Study#: 40093

Title of Study: Baby Basics Moms Club

Principal Investigator: Merry Mckenna

Discussion: None

Description of Action: Unanimously Approved

Study#: 40096

Title of Study: An Examination of Uninsured and Insured Cancer Patients in Virginia

Principal Investigator: Cathy J. Bradley, PhD

Discussion: None

Description of Action: Unanimously Approved

Study#: 40101

Title of Study: Cancer Epidemiology in Adventist- a low risk group

Principal Investigator: Gary E. Fraser, MD, PhD

Discussion: None

Description of Action: Unanimously Approved

Study#: 40102

Title of Study: Analysis of Urethral Exudates in Acute Gonorrhea

Principal Investigator: Alison Criss, PhD

Discussion: None

Description of Action: Unanimously Approved

Study#: 40114

Title of Study: Youth Risk Behavior Survey

Principal Investigator: Shanee Harmon

Discussion: The IRB Chair, Dr. Nair, advised the committee that as the Policy and Evaluation Division Director he has a conflict of interest in this project.

Description of Action: Study complete and closed

Study#: 40115
Title of Study: Exploring Risk and Perceptions of Risk in the Diagnosis of Breast Cancer in Smyth County, Virginia
Principal Investigator: Laura Jensen
Discussion: None
Description of Action: Study complete and closed

Study#: 40116
Title of Study: Health Effects: Air Pollution and Adverse Birth Outcomes in U.S
Principal Investigator: Naresh Kumar, PhD
Discussion: None
Description of Action: Study complete and closed

Study#: 40117
Title of Study: Community Outreach and Volunteer Training: Medical Reserve Corps Study
Principal Investigator: John Harrald
Discussion: None
Description of Action: Study complete and closed

Study#: 40118
Title of Study: Cancer Risk Among Firefighters and Emergency Service Rescuers and Officers Exposed to the World Trade Center Disaster
Principal Investigator: David J. Prezant, MD
Discussion: None
Description of Action: Unanimously Approved

Study#: 40119
Title of Study: Understanding Oral Health and Health Care in Lenowisco and Cumberland Plateaus Health Districts
Principal Investigator: Sarah Raskin, MPH
Discussion: None
Description of Action: Unanimously Approved

Study#: 40135
Title of Study: Impact of a Workplace Colorectal Cancer Screening Awareness Program
Principal Investigator: Resa M. Jones, MPH, Ph.D
Discussion: None
Description of Action: Study complete and closed

Study#: 40136
Title of Study: Social-spatial Risk and Protective Mechanisms in Urban

Principal Investigator: Adolescent Substance Use
Michael J. Mason, Ph.D
Discussion: The members had questions regarding how the new VDH Minor's Confidentiality Policy would impact this project. They agreed that a full discussion with clarification regarding the policy is in order.
Description of Action: Unanimously referred for full board review

Study#: 40138
Title of Study: Children's Understanding of Arrows
Principal Investigator: Krisztina Jakobsen
Discussion: None
Description of Action: Study closed; never started

Study#: 40142
Title of Study: Predictors of Communication and Sexual Decision Making Among Latino Couples
Principal Investigator: Jacqueline M. McGrath, Ph.D, PN, FNAP, FAAN
Discussion: None
Description of Action: Study complete and closed

OTHER (MINOR MODIFICATIONS, ETC):

Study#: 40068
Title of Study: Medical Monitoring Project
Principal Investigator: Dena Benson, MPH
Description: Changes to questionnaires and medical records abstractions data instruments as noted in submitted documentation.
Discussion: None
Description of Action: Unanimously Approved

Study#: 40102
Title of Study: Analysis of Urethral Exudates in Acute Gonorrhea
Principal Investigator: Alison Criss, Ph.D
Description: New sponsors were added and consent forms approved by UVA-HRS.
Discussion: None
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
Description: Enrollment is projected to start in October 2012, plus additional question has been added from the Youth

Discussion: Risk Behavior Surveillance System (YRBSS).
The members had questions regarding how the new VDH Minor's Confidentiality Policy would impact this project. They agreed that a full discussion with clarification regarding the policy is in order.

Description of Action: Unanimously referred for a full board review.

Study#: 40140
Title of Study: Lord Fairfax Health Department Youth Risk Behavior Survey

Principal Investigator: Charles Devine, MD
Description: Adds the school divisions of Page, Warren, Frederick, Clarke Counties and Winchester City; survey students in 8th and 11th grades; continue the YRBS distribution in the fall of 2012.

Discussion: None
Description of Action: Unanimously Approved

Study#: 40144
Title of Study: Project Connect: Evaluation of Public Health Partnership to Prevent Violence Against Women

Principal Investigator: Elizabeth Miller, MD, Ph.D
Description: This study will offer participants the option of completing the 90-day survey by telephone. The telephone method would only be utilized for women who are not able to return to clinic for their follow-up survey, especially in rural sites, which may not have access to internet and email.

Discussion: None
Description of Action: Unanimously Approved

Study#: 50084
Title of Study: Influenza Incidence Surveillance Project
Principal Investigator: Katie Kurkjian
Description: Extension of the project period, June 1, 2012 – May 31, 2013. Surveillance activities will be conducted from August 1, 2012-July 27, 2013; five of the six 2011-12 participating providers will be participating in the project from 2012-13; one additional practice will be recruited but has not been selected; specimen collection forms revised;

Discussion: None
Description of Action: Unanimously Approved

Study#: 50116
Title of Study: Alexandria Fire Department Closed Point of Dispensing Exercise 2012: Evaluating First Responder Attitudes

toward Medication Dispensed at a Closed Point of Dispensing.

Principal Investigator:

Stephen A. Haering, MD, MPH

Description:

The date of this exercise has changed from March 28, 2012 to June 6, 2012; the survey has some minor editing of phrases for clarification.

Discussion:

None

Description of Action:

Unanimously Approved

Meeting adjourned @ 1:05 pm.