REPORT TO THE COMMISSIONER:
ACTIVITIES OF
THE VIRGINIA DEPARTMENT OF HEALTH
INSTITUTIONAL REVIEW BOARD
CALENDAR YEAR 2013

Submitted by

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Chair
Virginia Department of Health Institutional Review Board

REPORT TO THE COMMISSIONER:
ACTIVITIES OF THE VDH IRB FOR CALENDAR YEAR 2013

Regulations for the conduct of human research, developed and approved by the Virginia Board of Health, became effective on July 1, 1993. The regulations apply to the department, including any local health department and to any facility operated, funded or licensed by the department which conducts or which proposes to conduct or authorize research which uses human participants. According to those regulations, prior to the initiation of a human research project a description of the proposed 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 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 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 46.110], 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 a designated IRB member or group of members reviews the proposed research rather than the entire IRB with final review and approval by the IRB Chair.

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".

Dev Nair, PhD, MPH, Director of the Division of Policy and Evaluation in the Office of Family Health Services continued to serve as the chair of the VDH IRB following his appointment by the State Health Commissioner in 2012.

The following is a summary of the activities and actions of the VDH IRB as per state "Regulations for the Conduct of Human Research" (12VAC5-20-50) during calendar year 2013.

Review Type	Approved	Not Approved
Full Review	1	0
Expedited Review	20	0
Exempt Review	17	0

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

A. Full Board Reviews

Study#: 40181
Title of Study: The Effect of Urban Empowerment Zones on Health Outcomes
Principal Investigator: John Cawley, PhD
Date approved: September 10, 2013
Description of Study: This study will investigate the effect of Empowerment Zones (EZ) on the health of individuals living in these Zones. The basic hypothesis to be tested is that birth outcomes, measured by low birth weight, improved in EZs compared to a control group of areas that applied for, but did not receive EZ status. The study will use vital statistics datasets from all 50 states, a proprietary dataset of all stores in which one can buy food in the largest 52 markets, and detailed, aggregate level data on socioeconomic status, basic demographics, and other population-level variables from the U.S. Census Bureau. Vital statistic data will be linked to census data. The board members unanimously agreed that the study had adequate data security and protections in place and agreed that the research proposal could be approved if de-identified census data is used pending additional information from Mr. Grossman and communication with Health Statistics. Mr. Grossman indicated that census-level data without addresses would be acceptable.

B. Expedited Reviews:

Study#: 40162
Title of Study: Pop-out Effects Infants
Principal Investigator: Krisztina Jakobsen, PhDA
Date Approved: January 25, 2013
Description of Study: The purpose of the 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 of age. Written parental consent is required. The speed of the infant responses as measured by eye movement will be recorded on the Tobii eye tracker. The

investigator plans to use vital records data to identify potential subjects for the study. The study protocol meets the requirements for the protection of human subjects, however, a determination as to whether this is an allowable use of vital records is subject to review by the VDH Division of Vital Records.

Study#: 40165
Title of Study: Spatial and Psychosocial Influences on Food Access in Rural Appalachia
Principal Investigator: Esther Thatcher, PhD, MSN, RN
Date Approved: January 23, 2013
Description of Study: The purpose of this study is to describe some important influences on food access and food choices in low-income rural Appalachian residents. Participants will be recruited through the Lee County Head Start and the Health Department. The proposed study includes a very detailed informed consent documents. Data will be collected through interviews and in-store surveys of available food products. Procedures are in place to protect the identity of the participants including the storage of all code-identified participant study data in a separate location. Electronic files will be stored on a password-protected computer and double-entered into password-protected files. This study presents low risk to the participants.

Study#; 40166
Title of Study: My Health Counts Population Health Study
Principal Investigator: Joseph P. McConnell, PhD
Date Approved: January 23, 2013
Description of Study: This study is proposed to evaluate the health benefits of six months participation in HDL's Wellness Program. The study population will be recruited from VDH employees with COVA Care insurance. A detailed informed consent is included. The study includes a health screening through an online survey, advanced lab testing with a report provided to participant, an offer for services to better understand personal risk factors and improve health, and follow-up testing to track and measure improvement. If information is published, the subject's identity will remain confidential. Adequate procedures are in place for handling significantly abnormal lab values that are deemed to be life-threatening. (IRB Chair reported that VDH senior leadership has decided that VDH will not participate in this study.)

Study#: 40167
Title of Study: Farmer's Market Subsidies as a Means to Improve Fruit and Vegetable Consumption Among Low-Income Pregnant Women: Acceptability and Feasibility
Principal Investigator: Audra Gollenberg, PhD
Date Approved: January 23, 2013
Description of Study: The project will assess the effect of a targeted farmers' market subsidy program for pregnant women participating in the WIC program in the Lord Fairfax Health District in order to better understand the acceptance/satisfaction with the program and the attitudes towards eating fresh fruits and vegetables. The voluntary participants will complete a questionnaire and will receive a $20 pre-paid voucher to be used at the Farmer's Market. At the next WIC meeting the participants will complete a follow-up questionnaire and will receive an additional $10 voucher. All information

provided by participants will be kept confidential and only be used for the purposes of the study. In order to link the study questionnaires with the vouchers and WIC forms it will be necessary to collect some identifying information. Once all forms are linked, the identifying information will be removed. Hard copy questionnaires will be kept in a locked cabinet and the electronic information will be de-identified.

Study#: 40168
Title of Study: Behavioral Health Integrated Centralized Intake in Virginia: Measuring Program and Community Impact
Principal Investigator: Sarah Kye Price, PhD, MSW
Date Approved: February 14, 2013
Description of Study This is a statewide program evaluation to determine to what extent the expansion of the centralized intake process, incorporating High Risk Behavioral Health Screening, improves access to home visiting services, recognition of and response to psychosocial risk compounding maternal and child health and community service linkage for women determined to be at elevated psychosocial risk. The research involves de-identified data and is largely a program evaluation, however it was submitted for expedited review because of the sensitive nature of data (mental health, substance abuse, interpersonal violence) in an at-risk population (pregnant women). A request for waiver of informed consent and the HIPAA process was requested and has been previously approved by the Virginia Commonwealth University (VCU) IRB. The same request is submitted to the VDH IRB. The researchers have taken precautions to de-identify the data in order to maximize the privacy of women who receive services. Asking women to sign informed consent would reveal their identities to the research team and may put them at more risk. Adequate protections are in place to minimize the risk to the participants.

Study#: 40169
Title of Study: Implementation of Behavioral Health Integrated Centralized Intake in Virginia: Process and Outcomes of a Statewide MCHIEV Expansion Project
Principal Investigator: Sarah Kye Price, PhD, MSW
Date Approved February 14, 2013
Description of Study: The purpose of the study is to better understand the process of implementing behavioral health integrated centralized intake in Virginia's maternal and child health home visiting programs. The study population includes employees of MCHIEV home visitation programs, community professionals working with pregnant and post-partum women as well as pregnant and post partum women themselves. Written individual informed consent will be required from each participant. Baseline interviews will be conducted within the communities under consideration for expansion. Formative and outcome evaluation case studies will be generated within the study groups (new, augmented and usual care). Program participant stakeholders will be randomly selected. This study involves minimal risk to participants in that the interviews pertain to the implementation process. Adequate procedures are in place to maintain the confidentiality of the data.

Study#: 40170
Title of Study: Improving Nutrition Knowledge in WIC Participants Through "Health Bites"
Principal Investigator: Cynthia Rubenstein, PhD, RN, CPNP-PC
Date Approved: February 19, 2013
Description of Study The purpose of the study is to evaluate the self-efficacy and general nutrition knowledge of WIC participants completing the online "Health Bites" nutrition modules. All WIC participants are required to complete nutrition education at specified time periods to qualify for their WIC financial support. Participants can complete the requirement on line through "Health Bites" or through face-to-face/group educational sessions. The "Health Bites" modules include a pretest and posttest. The study objective is to compare pretest and posttest measures of self-efficacy and basic knowledge specific to the module that the WIC participant has selected. The grant funding for "Health Bites" requires an evaluation of the effectiveness of the intervention through an analysis of pretest and posttest. The purposed research project fulfills this requirement. The pretest/posttest analysis will be completed on a sampling of modules that have a minimum number (n=50) of participants completing them. The only identification will be a WIC Family ID number. The researchers will not have access to the WIC Family ID number or any demographic data. There is no additional risk for participants. Consent is not required since nutrition education is a WIC requirement and choosing to obtain credit for nutrition education through "Health Bites" is voluntary.

Study#: 40171
Title of Study: The Behavioral Impact of Poor Birth Outcomes on Subsequent Pregnancies: A Study of Virginia PRAMS 2007-2010
Principal Investigator: Sara Varner, BA, (MPH Candidate)
Date Approved: February 19, 2013
Description of Study: The purpose of this study is to examine cigarette smoking and alcohol use among pregnant women with a previous live birth with poor outcomes (low weight birth or preterm) compared to women with previous normal (full term or adequate birth weight) birth outcomes. The study uses secondary data from the Pregnancy Risk Assessment Monitoring System (PRAMS) and the birth certificate. There will be no direct interaction with research participants. No identifying data will be used in the analysis. Data will be password-protected and stored in locked rooms. At the end of the study the researchers' datasets will be destroyed and the original data will be returned to VDH.

Study#: 40172
Title of Study: Infant Feeding Practices and Beliefs of Latina Mothers
Principal Investigator: Suzanne Ameringer, PhD, RN
Date Approved: March 7, 2013
Description of Study: The purpose of this research is to explore the factors that contribute to Latina mothers overfeeding practices and to what extend these feeding practices are determined by the socioeconomic context and cultural traditions with the family. A sample of 90 immigrant low-income Latin origin mothers and their infants will be recruited from the Child Development Resources of Williamsburg and the Peninsula WIC offices. Half the sample will be mothers with infants whose weight is $\leq 85^{th}$

percentile and half the sample will be mothers with infants whose weight is $\geq 85^{th}$ percentile. Interviews will be conducted using a 70 page instrument. Written informed consent is required however participants with low literacy will have an opportunity to receive oral consent and sign it with a witness. Provisions are adequate for the protection of the participant's identity. Data will be kept in a locked file cabinet.

Study#: 40173
Title of Study: The American Cancer Society Cancer Prevention Study-3 Registry Linkage
Principal Investigator: Alpa V. Patel, PhD
Date Approved: March 18, 2013
Description of Study: The purpose of this study is to link participants in a large prospective nationwide study (Cancer Prevention Study-3) with the state cancer registry data in order to identify incident cancers and obtain diagnostic and prognostic information necessary to conduct epidemiologic analyses related to cancer. This national study is expected to include 300,000 men and women ages 30-65 with no history of cancer. The participants will provide informed consent, a waist measurement, and a blood sample and complete a brief questionnaire. Additional questionnaires will be completed periodically. The participants will be followed for at least 20 years. The data linkage project will involve a dataset of current study enrollees securely transferred to the Virginia Cancer Registry for a probabilistic match to determine cancer incidents. Provisions are adequate for the protection of the participant's identity. Data files that include identifiers necessary for follow-up are only accessible to select Study Management Group staff involved in these activities. Data files are password protected and all paper documents containing identifiers are shredded except those needed for later use. All documents are contained in a locked document room with limited staff access.

Study#: 40175
Title of Study: Evaluating Effectiveness of a Third Dose of Measles-Mumps-Rubella (MMR) Vaccine for Mumps Outbreak (Control, Henrico County and Richmond City, Virginia
Principal Investigator: Laura Ann Nicolai, MPH
Date Approved: April 10, 2013
Description of Study: This is a VDH study to determine the effectiveness of a third dose of measles-mumps-rubella (MMR) vaccine in controlling a university-based outbreak of mumps. The vaccine will be offered to the students and followed by a survey 2 to 3 months later to determine the effectiveness of the third MMR vaccination. The consent form includes a separate section requesting permission for VDH to verify previous vaccination history with the University Student Health Center. All physical and electronic data will be stored in compliance with VDH Policy in a locked file cabinet with limited access to staff. All publications/reports will comply with VDH procedures on aggregate data release to ensure that individuals cannot be identified. The study poses minimal risk to the subjects.

Study#: 40176
Title of Study: Improving Access to Prenatal Care
Principal Investigator: Elizabeth D. Beasley, MPH
Date Approved: May 4, 2013

Description of Study: The purpose of this study is to identify specific barriers to accessing prenatal care in the Thomas Jefferson Health District. The target population is mothers and pregnant women between 15 and 35 who reside in traditionally lower-income areas of Charlottesville, Nelson and Louisa counties. Participants will be recruited through flyers distributed in local health departments, community partner organizations, prenatal clinics and WIC clinics. Information collected during the focus groups and questionnaires includes attitudes and experiences regarding prenatal care providers, and patient levels of health knowledge of the importance of prenatal care. No identifiable information will be collected. Participating minors will be required to provide a signed parental consent form. No personal identifiable information is collected during the focus group. Recording and individual questionnaires will be destroyed after the report is written. Digital information will be stored in a password protected folder on a secure network drive.

Study #: 40177
Title of Study: Feasibility Study of Community Garden Project to Improve Nutrition for WIC Clients
Principal Investigator: Janice Lorraine Taylor Peters, MPH
Date Approved: July 9, 2013
Description of Study: The goal of this project is to gain insight/feedback on how access to community gardens, farmers' markets and other sources of fresh vegetables and fruits will improve the nutrition of Tazewell County, Virginia residents. WIC participants will be surveyed to assess their knowledge, attitudes and beliefs around access to fresh foods. The participants' names will not be recorded. The project will also include informal interviews of key community leaders including business owners, local government agency staff and local service organization representatives about the feasibility of expanding the community garden model to serve additional people and more locations throughout the county. The final report will be submitted to the Tazewell County Health Department and Liberty University.

Study#: 40178
Title of Study: Talking Health-Main Trial
Principal Investigator: Jamie Zoellner, PhD, RD
Date Approved: July 12, 2013
Description of Study: This is an 18 month randomized control intervention funded by NIH/NCI to decrease sugar sweetened beverage intake among adults in eleven counties in Southwest Virginia. Participants must be 18 years of age or older, English speaking, non institutionalized and consuming more than 200 calories per day of sugar-sweetened beverages per day and be without medical conditions in which physical activity would be contraindicated. Recruitment will be via word of mouth, recruitment flyers, newspaper advertisements and community meetings. An oral consent statement will be read and signed consent will be obtained from each participant. Any potential participant having repeated measures of systolic blood pressure at or above 160 or diastolic blood pressure at or above 100 will be required to obtain a medical release to participate. The intervention group will receive three nutrition education sessions focusing on reducing sugar-sweetened beverage consumption. The control group will receive three physical activity education sessions. Periodic telephone calls to both groups will document sugar-sweetened beverage consumption. Data will be maintained in a

locked file cabinet. Plans include publishing summary/aggregate findings in a peer reviewed journal. Research staff has completed training in the protection of human subjects.

Study#; 40179
Title of Study: Virginia Youth Survey
Principal Investigator: Danielle Henderson
Date Approved: July 31, 2013
Description of Study: This is a nationally supported survey that monitors six categories of health-risk behaviors among youth, including behaviors that contribute to unintentional injuries and violence; tobacco use; alcohol and other drug use; unhealthy dietary behaviors; physical inactivity; obesity and asthma. The survey will be conducted in randomly selected middle and high schools. A parental consent form will be provided to parents with information regarding the survey and an option to opt out. Survey procedures are designed to protect student privacy. Participation will be voluntary and no identifying information will be collected. Scanning and analysis of the survey will be completed by Westat and the Centers for Disease Control. Once results are final, a press release will be developed informing parents, school officials and other interested parties that the results are available on the VDH website.

Study#: 40180
Title of Study: Survey of the Food Environment in Lenowisco Health District, VA
Principal Investigator: Esther Thatcher, MSN, RN, PhDc
Date Approved: August 12, 2013
Description of Study: The purpose of the study is to determine the availability and price of certain food items in the area. The data will be used to plan public health programs to improve nutrition in Southwest Virginia. A standardized instrument will be used to collect data from individual stores. The store manager will be informed of the study and request permission to collect data regarding the availability and price of items. Food store names and location information will be maintained in password protected file and/or a locked file drawer. De-identified data may be shared with other agencies for planning purposes.

Study #: 40183
Title of Study: HIV Systems Linkages and Access to Care Initiative
Principal Investigator: Anne Rhodes
Date Approved: October 13, 2013
Description of Study: The purpose of this study is to evaluate the effectiveness of innovative linkage and retention strategies of HIV care outcomes in order to improve access to and retention in high quality, competent HIV care. The study uses routinely collected client-level data. The study represents minimal risk to participants. Additionally, safeguards are in place to reduce breaches of confidentiality and/or identification of individuals who are HIV positive.

Study #: 40184
Title of Study: iChoose-Evaluation of a Childhood Treatment Program in the Dan River Region
Principal Investigator: Jamie Zoellner, PhD, RD
Date Approved: October 22, 2013
Description of Study: The study represents a systems-based approach to address childhood obesity in the Dan River Region. The study population includes English speaking children aged 8-12 with BMI >85th percentile who receive care at either the Virginia Department of Health's Pittsylvania Danville Health District or the Children's Health Care Center. Both children and parents will participate in a health screening and three months of health education classes, including the children participating in physical activity. Telephone/emails to participants will provide support on reaching eating and physical activity goals. Periodic newsletters with health and physical activity information will also be sent to participants. At the program's end, a health screening and exit survey will be conducted. The study includes adequate informed/assent and presents minimal risks for participants. Provisions to protect privacy of subjects and confidentiality of data are in place. Any study findings will only include de-identified data.

Study #: 40185
Title of Study: Virginia Cancer Health Disparities
Principal Investigator: Brandy L. Edwards, MD
Date Approved: November 12, 2013
Description of Study: The purpose of this study is to map cancer incidence rates, mortality rates, and late stage diagnosis rates by census tract and/or county using GIS for nine common malignancies in Virginia. Any identified geographical cancer clusters will be evaluated for exposure to environmental hazards. The quality of treatment received by colorectal and breast cancer patients and disparities in long-term survival of breast cancer patients will also be assessed. Retrospective data from the Virginia Cancer Registry for 2000-2012 will be linked to data from the University of Virginia (UVA) Clinical Data Repository, the National Death Registry, and the US Census. Individual data will not be reported – all data will be reported at county or census tract levels. Identifiable data will be stored on a server through the UVA Department of Bioinformatics and protected by a firewall and accessed through encrypted VPN. Following linkage all personal identifiers will be removed from the data set and stored separately. The study presents minimal risk to individual participants. The study was reviewed and approved by the University of Virginia (UVA) IRB.

Study #: 40186
Title of Study: Delivery Options and Barriers to Prenatal Care for Women in Poverty in the Central Shenandoah Health District
Principal Investigator: Maria Gilson DeValpine, RN, MSN, PhD
Date Approved: November 5, 2013
Description of Study: The purpose of this study is to gain an understanding of the extent of prenatal care and delivery services available in the Central Shenandoah Health District and the barriers, if any, to using existing services. The findings will be used to develop program and policy recommendations to alleviate any barriers and

improve access. Providers, public health nurses and recent postpartum clients of the health district will be interviewed. The women's consent forms and the completed surveys will be stored separately in locked files at James Madison University. No identifying data will be collected on the surveys or included in any reports or presentations. The study poses only minimal risk to the respondents.

C. Exemption Reviews

Study#: 50138
Title of Study: Cancer Survival in Appalachia
Principal Investigator: Bin Huang, DrPH
Date Approved January 9, 2013
Description of Study: This is a multi-state study of cancer survival in West Virginia and portions of 12 Appalachian states including Virginia. Cancer registry data will be linked with National Death Index (NDI) data to determine factors that impact cancer survival rates. The Virginia Cancer Registry data will be a part of this study. The study uses existing data and the subjects will not be identified. All data transferred between agencies will be encrypted.

Study#: 50139
Title of Study: Behavioral Health Integrated Centralized Intake: Assessing Provider Readiness and Perceptions of Behavioral Health Risk Screening
Principal Investigator: Sarah Kye Price, PhD, MSW
Date Approved: January 16, 2013
Description of Study: This is a part of a larger study approved by VCU IRB. The purpose of the study is to assess Virginia's home visitation providers to gather baseline data regarding their readiness, attitudes, knowledge, and experiences with perinatal depression and behavioral health risk screening. The data will be collected through a de-identified electronic survey. No risks to human subjects were identified. The de-identified data will be presented in aggregate form. The electronic records will only be available to the PI and staff and access is password protected.

Study#: 50140
Title of Study: Exposure-Response Analysis for North American Vinyl Chloride Workers
Principal Investigator: Kenneth Mundt, PhD
Date Approved: January 16, 2013
Description of Study: This study is an update of a retrospective cohort study of 10,109 male employees who worked at any North American Vinyl Chloride factories between 1942-1972 to determine the relationship between vinyl chloride exposure and causes of death – specifically causes combined with cancers, site-specific cancers and various non-malignant causes of death. Existing data will include the Epidemiological Research Database of the Social Security Administration, the National Death Index and death certificates. Confidentiality of identifiable information will be protected with

passwords and restricted access. Identifiable data will also be separate from other project files and hard copy files will be stored in locked cabinets. Findings from the research will be presented in aggregate format.

Study#: 50141
Title of Study: Rabies Post-Exposure Prophylaxis Epidemiology in Fairfax County, 2010
Principal Investigator: Steven Rekant, DVM Student
Date Approved: January 31, 2013
Description of Study: The purpose of the study is to review and analyze data previously collected for public health purposes by the Fairfax County Health Department regarding Rabies Post-Exposure Prophylaxis. The study is a case review of persons that were potentially exposed to Rabies. Information will be used as a guide for future education and outreach programs related to rabies exposure. No human subjects will be contacted, surveyed or actively used in the study. The database will be de-identified prior to sharing with the principal investigator.

Study#: 50142
Title of Study: Exposure Reconstruction and Updated Mortality Analysis for the US Industry-Wide Carbon Black Mortality Cohort Study
Principal Investigator: Kenneth Mundt, PhD
Date Approved: January 31, 2013
Description of Study: This follow-up study will examine mortality patterns from lung cancer, non-malignant respiratory diseases, and cardiovascular diseases of employees of carbon black production facilities. The secondary data will come from death certificates and the National Death Index (NDI) database. No more than minimal risk. The study was previously approved by ENVIRON IRB. Adequate security such as personal identifiers kept in secure, password- protected database and a data destruction plan is in place.

Study#: 50143
Title of Study: Behavioral Risk Factor Surveillance System (BRFSS)
Principal Investigator: Danielle Henderson
Date Approved: February 14, 2013
Description of Study: The BRFSS is a CDC-funded cross-sectional telephone survey of adults that collects information on health risk behaviors, preventive health practices, and health care access primarily related to chronic disease an injury. The questionnaire is comprised of core questions and optional modules that have been approved through the CDC IRB along with the methods. Virginia is including 3 state-added series of questions regarding cognitive impairment, oral health and disability. Data sets do not contain any personal identifying data and data are aggregated. No identified risk to human subjects.

Study#: 50144
Title of Study: Alexandria Redevelopment Housing Authority (ARHA) Healthy Air Study
Principal Investigator: Stephen A. Haering, MD, MPH, FACPM

Dated Approved: February 15, 2013
Description of Study: The purpose of the study is to measure the ARHA residents' exposure to and attitudes about environmental tobacco smoke, specifically with regard to how they might feel about living in smoke-free buildings. Surveys will be administered to a systematic-random sample of residents by trained interviewers. Verbal consent will be obtained before participation and information regarding the survey will be available. The project presents less than minimal risk to participants. Participation is voluntary and anonymous. Participants may skip any question and no identifying information will be collected.

Study #: 50145
Title of Study: Every Woman's Life-Is it Really an Early Detection Program?
Principal Investigator: Melanie Dempsey
Dated Approved April 10, 2013
Description of Study: This study will analyze data from the Every Woman's Life (EWL) program to investigate/analyze the profile of women enrolled in the program for evidence and trends in early detection and the establishment of a medical home. The analysis will provide information regarding the differences between EWL women and those not served by the program. The study will use existing EWL data, documents, records and specimens. No informed consent is needed. EWL data is maintained in software provided by the Centers for Disease Control and Prevention (CDC). Individuals will not be identified directly or indirectly.

Study #: 50146
Title of Study: Birth Certificate and Fetal Death Certificate Data Matching for the Post-Licensure Rapid Immunization Safety Monitoring Program (PRISM)
Principal Investigator: Nandini Selvam, PhD, MPH
Date Approved: April 18, 2013
Description of Study: Multi-state project funded by US Food and Drug Administration (FDA) to evaluate linkage rates for mothers and infants identified using health plan data and linkage rate of health plan data to birth and fetal death certificate data; to describe characteristics and birth outcomes of population of mothers and infants identified for vaccine safety surveillance through the Mini-Sentinel Post-Licensure Rapid Immunization Safety Monitoring (PRISM) system; to evaluate patterns and trends in vaccine and medication use during pregnancy and birth outcomes as a component of safety surveillance activities of the Mini-Sentinel Program; to evaluate the association between specific vaccines used during pregnancy and birth outcomes. Approximately 75,000 Virginia births are in their administrative claims data between 2004 and 2011. No informed consent necessary, secondary data used throughout the study. Data security is adequate. All the data will be incorporated as part of an on-going and continuous immunization safety monitoring program in pregnant women.

Study#: 50147
Title of Study: Epidemiologic Study of One Million U.S. Radiation Workers
Principal Investigator: Michael Mumma

Date Approved: April 26, 2013
Description of Study: This study will provide an evaluation of possible risks associated with low-dose radiation exposures over a prolonged period of time. The proposal includes linkage with Virginia Vital Statistics computer files to identify additional deaths among one million early radiation workers not identifiable through linkages with the Social Security Administration Master Death file to obtain the cause of death for these workers. All computer data files will be stored on password protected computers in a locked office. Personal information will be excluded from data analysis file to ensure confidentiality of the study participants. No publication or presented statistical tabulation will contain names or other personal characteristics that would enable identification of the study subjects. Aggregate data will be used in reports and tables.

Study#: 50148
Title of Study: Health System Delivery Factors Associated with Influenza Vaccination Coverage during the H1N1 2009-10 Pandemic Response in Virginia
Principal Investigator: Brittany L. Foster (under the supervision of Dr. Robert D. Bradshaw)
Date Approved: May 14, 2013
Description of Study: This is a VDH study of influenza vaccination data in localities to determine coverage rates for school age children and the methods used to deliver the vaccinations. No informed consent is required; using existing data. Identifying information will not be used and all data is stored with password protection.

Study#: 50149
Title of Study: Community Assessment for Public Health Emergency Response (CASPER) in Portsmouth Health District
Principal Investigator: Katie Kurkjian, DVM, MPH
Date Approved: May 16, 2013
Description of Study: Epidemiologic methods will be used to collect household level information for community health assessment. Households will be randomly selected based on a sample of Census blocks. Following informed consent, respondents (age 18 years or older) will be interviewed regarding health assessment. All data will be stored and secured in accordance with the VDH Confidentiality Policy. Data will be analyzed primarily using ArcGIS software. A final report will be distributed to stakeholders along with training and questionnaire materials that can be used by other jurisdictions interested in performing this kind of assessment. There is minimal risk to the subjects.

Study#: 50150
Title of Study: Comparison of Risk Factors Associated with Unilateral and Bilateral Hearing Loss Identified by Newborn Hearing Screening
Principal Investigator: Kelly M. Dodson, MD
Date Approved: June 6, 2013
Description of Study: This is a retrospective review of children with confirmed hearing loss identified through Virginia's universal newborn hearing screening program

from 2002-2008. Outcomes of interest are subjects with unilateral and bilateral hearing loss and the presence or absence of risk factors and co-occurring birth defects. Aggregate data summary tables will be prepared by VDH staff. The tables will be used by the research team to prepare a manuscript for publication in a peer-reviewed journal in collaboration with VDH staff. No risks to subjects are identified.

Study#: 50151
Title of Study: Attitudes about Breast Cancer in Rural Appalachia
Principal Investigator: Santana VanDyke (Dr. Madelyn Shell, Advisor)
Date Approved: July 12, 2013
Description of Study: The purpose of the study is to investigate health behaviors and attitudes such as breast cancer fears and general health concerns and the decision to get a mammogram. Data will be collected via survey at various health fairs during which mammograms will be available. The survey responses of women choosing to receive a mammogram and those choosing to not receive a mammogram will be compared. No identifying data will be collected.

Study#: 50152
Title of Study: Evaluating Attitudes toward Disease Prevention Behaviors among Staff at Long-term Care Facilities and Schools in the City of Alexandria
Principal Investigator: Stephen A. Haering, MD, MPH, FACPM
Date Approved: September 24, 2013
Description of Study: The study will assess attitudes that staff at long-term care facilities and schools in Alexandria have toward disease prevention behaviors, such as seasonal flu vaccine, hand hygiene and cough etiquette. Online and paper surveys will be distributed to school and long-term care facility staff. Participation is voluntary and no identifiable information will be collected.

Study#: 50154
Title of Study: Aetna-Birth Certificate and Fetal Death Certificate Matching for the Post-Licensure Rapid Immunization Safety Monitoring (PRISM) Program
Principal Investigator: Cheryl McMahill-Walraven, MSW, PhD
Date Approved: November 21, 2013
Description of Study: This is part of a national study that proposes to develop the data infrastructure to evaluate potential associations between vaccine exposure of pregnant women and adverse events occurring in mothers and infants. The PRISM program currently contains health insurance data from four large national health insurance plans and vaccination data from Immunization Systems from health departments in seven states and New York City. The Virginia study population includes Aetna members who delivered an infant in Virginia between 2008-2012. Data from VDH Vital Statistics on birth and fetal death will be linked to Aetna's membership and claim utilization records to aid in the public health surveillance activities under the direction of the Federal Drug Administration (FDA). Aetna will provide identifying information to the VDH Division of Health Statistics for the data linkage. Once the linkage is completed, all non-essential identifying data will be excluded. Aetna's data

security includes the storage of all data on separate servers with password protected access. All employees are required to have annual privacy and confidentiality training.

Study #: 50155
Title of Study: Critical Congenital Heart Disease Screening Chart
Principal Investigator: Sarah Manglicmot, BSN, RN
Date Approved: December 9, 2013
Description of the Study: The goal of this study is to test a new version of a chart for the oximetry screening and early detection of Critical Congenital Heart Disease (CCHD) in newborns. A failure modes and effects analysis (FMEA) to validate the tool for accuracy will be conducted in collaboration with Henrico Doctors' Hospital. The research involves the study of existing documents by providers and clinical experts.

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 2013		
Committee Members	**Qualifications for Service**	**Institutional Affiliation**
IRB CHAIR		
Dev Nair	PhD – Clinical Psychology, MPH – Management and Policy Current position - Director, Division of Policy & Evaluation	Virginia Department of Health
VOTING MEMBERS		
Jeffrey Stover	MPH - Public Health Epidemiology Current Position - Director, STD Surveillance Operations & Data Administration	Virginia Department of Health
Ana Lizzette Colon	MPH - Epidemiology Current Position - Regional Surveillance Coordinator	Virginia Department of Health, Eastern Region Field Office
Bethany J. Geldmaker	PhD - Nursing & Child Health Care Current Position – Program Consultant, Child Health	Virginia Department of Health
Ronnette Langhorne	RN, MSN Current Position - Nurse Manger	Norfolk Virginia Department of Health
Janice Hicks	PhD - Social Policy and Social Work Current Position – Policy Analyst	Virginia Department of Health
J. Elisha Burke (Resigned effective January 7, 2013)	Dr. of Ministry – Theology Current Position - Director of Health Ministry	Baptist General Convention of Virginia
Cecilia Barbosa	MPH (VCU Doctoral Candidate)	Community Representative
ALTERNATE MEMBERS		
Vacant		

Virginia Department of Health
Institutional Review Board
January 7, 2013
MINUTES

Members Present: Chair Dev Nair (arrived @ 10:33) Elisha Burke (arrived @ 10:20) Ana Colon (arrived @ 10:34) Cecilia Barbosa (arrived @ 10:37)

Absent Members: Bethany Geldmaker, Ronnette Langhorne, Jeffrey Stover

Staff Present: Janice Hicks, Tywanda Bolden

General Items/Announcements

- The meeting was convened at 10:40 AM. A quorum was present.
- Minutes from October 1, 2012 meeting and the Full Board Review Minutes from October 24, 2012 will be voted on electronically through email.
- The role of the IRB and the VDH policy on Providing Services to Minors will be discussed on 2/13/13 by polycom in order for all members to be involved.
- General IRB Policy comments to Janice by the end of the week.
- Recognition of Dr. Elisha Burke for his tenure on the VDH IRB.
- Schedule Meeting for **2013**
  - **April 8**
  - **July 8**
  - **October 7**
- Future IRB quarterly meetings will begin at 10:00 AM instead of 10:30 A.M.

PRESENTATION OF NEW PROTOCOLS- EXEMPTION REVIEWS:

Study#: 50135
Title of Study: Using GI Syndrome Data as an Early Warning Tool for Norovirus Outbreak Activity
Principal Investigator: Erin Austin
Primary Reviewer: Ana Colon
Date Approved: October 16, 2012
Description: Study of existing data; research designed to study large scale anonymous vital records and registry data; 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.
Description of Action: Agreed

Study#: 50136
Title of Study: Virginia Early Childhood Needs Assessment

Principal Investigator: John Almarode, PhD
Primary Reviewer: Ronnette Langhorne
Date Approved: December 5, 2012
Description: 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). The study poses only minimal risk; research uses existing de-identified dataset and no contact with the actual client. The researcher has requested permission to use the dataset.
Description of Action: Agreed

Study#: 50137
Title of Study: Vote & Vax Virginia 2012
Principal Investigator: Joseph Hoyle
Primary Reviewer: Elisha Burke
Date Approved: November 28, 2012
Description: 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. This project is consistent with CDC recommendations for a community-based effort to increase influenza vaccination rates. Responses from participants will be recorded so that human subjects cannot be identified. This is a minimal risk project.
Description of Action: Agreed

PRESENTATION OF NEW PROTOCOLS – EXPEDITED REVIEWS:

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
Primary Reviewer: Ana Colon
Date Approved: October 23, 2012
Description: The purpose of this project is to better understand the barriers and facilitators to breastfeeding and begin to engage the community in developing strategies to address barriers in order to improve breastfeeding rates. The subjects of the focus group study are Non-Hispanic African-American first-time mothers of children who are less than two year old, recipients of public assistance, at least 18 years old, Richmond City residents and English speaking. Participants will be asked to sign a consent form. Staff will be required to sign a statement of confidentiality. The focus groups will be recorded with participants identified by an assigned code. The recordings will be sent to a transcription service and will be destroyed once the study is completed. Files will be password protected.
Description of Action: Agreed

Study#: 40158
Title of Study: Camp Lejeune Health Survey
Principal Investigator: Perri Ruckart, MPH
Primary Reviewer: Elisha Burke
Date Approved: October 25, 2012
Description: Survey is being conducted by Agency for Toxic substances and Disease Registry (ATSDR) to assess if there is an association between exposure to the contaminated drinking water at Camp Lejeune and cancer and other specified health conditions. The analyses will focus on reported diseases of interest that are confirmed by medical records and cancer registries. Informed consent will be obtained; no direct benefits to the subjects from taking part in the study; findings will be available in 2014 through scientific journals and the ATSDR Camp Lejeune website.
Description of Action: Agreed

Study#: 40159
Title of Study: Companion Animals as Sentinels of Human Disease: A Community-based Study
Principal Investigator: Francois Elvinger, Dr., PhD
Primary Reviewer: Bethany Geldmaker
Date Approved: November 7, 2012
Description: The purpose of this study is to determine if there is a correlation between pet health and any human public health trends that exist in the Lenowisco Health District. A survey will be administered to a member of 75 households that owns at least one companion animal that can be handled safely. Participants will be recruited by word of mouth and flyers. A series of questions regarding the health history of each pet and a physical exam of the pet will be conducted. Participants will be provided information on the study and sign a consent form. The results of the survey and exam will be compiled in a spreadsheet and stored on the investigator's computer for analysis.
Description of Action: Agreed

Study#: 40160
Title of Study: An Academic-Community Partnership to Address Health Disparities in Infant Mortality
Principal Investigator: Audra Gollenberg, PhD
Primary Reviewer: Bethany Geldmaker
Date Approved: October 16, 2012
Description: The purpose of the study is to identify and address disparities in infant mortality in the Lord Fairfax Health District of Virginia. The study will use individual and group-interview methodologies to gather information on community strengths and weakness, community perceptions and resources needs of the community in order to develop a tailored intervention strategy. Informed consent will be required from all participants before the interviews are conducted as well as permission to record the sessions. All information collected as a part of the study will be de-identified; only the PI will have access to the information which will be stored on a computer and password protected.
Description of Action: Agreed

Study#: 40162
Title of Study: Pop-out Effects in Infants
Principal Investigator: Krisztina Jakobsen, PhD
Primary Reviewer: Ana Colon
Date Approved: January 25, 2013
Description: 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. Written parental consent is required. The infant will be seated in the parent's lap or an infant seat in front of a computer screen. The speed of the infant responses as measured by eye movement will be recorded on the Tobii eye tracker for approximately 5 to 10 minutes. Measures are in place to cease the exposure if infant becomes fussy or disinterested. Results of this study may be presented in aggregate form conferences or published in a manuscript. They are seeking VDH IRB approval because the investigator would like to access vital records to identify potential subjects for the study. The study protocol meets requirements for the protection of human subjects, however, a determination as to whether this is an allowable use of vital records data will need to come from the Department of Vital Records.
Description of Action: Agreed

Study#: 40163
Title of Study: A Pilot of SBIRT for Risky Drinking and Alcohol-Exposed Pregnancy Risk
Principal Investigator: Karen S. Ingersoll, PhD
Primary Reviewer: Bethany Geldmaker
Date Approved: December 5, 2012
Description: 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. The estimated number of participants is 40 women at least 18 years of age attending a family planning or STD clinic at the Virginia Department of Health Waynesboro Women Health Clinic. Pregnant women or those planning to get pregnant within the next 3 months will be excluded from the study. Participants are required to sign a consent form which will be maintained separately from the questionnaires. Each form will be de-indentified and contain a unique numeric ID; stored in a locked filing cabinet in the PI's office. Participants will complete a screening and a baseline questionnaire and receive screening, brief intervention, and referral to treatment services from their current clinic health providers. They will also receive a one week telephone based follow-up. The data will be password protected on a secure network only accessible to the research team. The project provides an incentive for the participants.
Description of Action: Agreed

Study#: 40164
Title of Study: Diabetes among Sworn Public Safety Officers;

Control, Compliance and Cost
Principal Investigator: Heidi A. Kulberg, MD, MPH
Primary Reviewer: Bethany Geldmaker
Date Approved: December 13, 2012
Description: The purpose of this study is to determine the occurrence, patient compliance and costs of diabetes in sworn public safety officers. A sample of 548 officers (195 from the fire department, 187 from the police department and 166 from the sheriff's department) health records will be analyzed to assess the occurrence, compliance and costs related to diabetes. This is a retrospective chart review and does not require informed consent. The information will be de-identified and findings will be presented in aggregate form. The findings will be presented to the Chesapeake Occupational Health Services Clinic, Eastern Virginia Medical School Health Professions Department and potentially city legislators via PowerPoint presentation, written report and poster board display.
Description of Action: Agreed

PRESENTATION OF NEW PROTOCOLS – FULL BOARD REVIEW:

Study#: 40161
Title of Study: Motivational Interviewing Integrated with Social Network Counseling for Teens
Principal Investigator: Michael J. Mason, PhD
Date Approved: December 14, 2013
Discussion: A full board review meeting was held on October 24, 2012. The minutes from that meeting are attached.
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: None
Description of Action: Agreed

Study#: 40120
Title of Study: Endometrial Cancer in Virginia
Principal Investigator: Madeleine Courtney-Brooks, MD
Discussion: A letter from the IRB Chair resulted in the PI responding with the continuation form.
Description of Action: Agreed

Study#: 40125
Title of Study: The Vaginal Microbiome: Disease, Genetics and the Environment
Principal Investigator: Gregory Buck, PhD
Discussion: None
Description of Action: Agreed

Study#: 40136
Title of Study: Social-spatial Risk and Protective Mechanisms in Urban Adolescent Substance Use
Principal Investigator: Michael J. Mason, PhD
Discussion: Discussed in the full board review meeting on October 24, 2012. Minutes are attached.

Description of Action: Agreed

Study#: 40137
Title of Study: The Association between Maternal Obesity and Adequacy of Prenatal Care
Principal Investigator: Saba Masho, MD, MPH
Discussion: None
Description of Action: Agreed

Study#: 40139
Title of Study: Garret Lee Smith Youth Suicide Prevention Program Evaluation
Principal Investigator: Heather Funkhouser Board
Discussion: None
Description of Action: Agreed

Study#: 40140
Title of Study: Lord Fairfax Health Department Youth Risk Behavior Survey
Principal Investigator: Charles J. Devine III, MD
Discussion: None
Description of Action: Agreed

Study#: 40141
Title of Study: Response Program Evaluation
Principal Investigator: Stephanie Goodman, MPH
Discussion: None
Description of Action: Study closed

Study#: 40144
Title of Study: Project Connect: Evaluation of Public Health

Partnership to Prevent Violence against Women
Principal Investigator: Elizabeth Miller, MD, PhD
Discussion: None
Description of Action: Agreed

Study#: 40147
Title of Study: Assisted Reproductive Technology& the Risk of Childhood Cancer
Principal Investigator: Barbara Luke, ScD, MPH
Discussion: None
Description of Action: Agreed

OTHER (MINOR MODIFICATIONS, ETC):
Study#: 40125
Title of Study: The Vaginal Microbiome: Disease, Genetics and the Environment
Principal Investigator: Gregory Buck, PhD
Description: The recruitment of additional twin pairs for the project; listing of only Gregory Buck, PhD as the PI/PD; clarification of the number of participants targeted in the project.
Discussion: None
Description of Action: Agreed

Study#: 40136
Title of Study: Social-spatial Risk and Protective Mechanisms in Urban Adolescent Substance Use
Principal Investigator: Michael J. Mason, PhD
Description: Enrollment is projected to start in October 2012; additional questions have been added from the Youth Risk Behavior Surveillance System (YRBSS).
Discussion: None
Description of Action: Agreed

Study#: 40139
Title of Study: Garrett Lee Smith Youth Suicide Prevention Program Evaluation
Principal Investigator: Heather Funkhouser Board, MPH
Description: A new interim Principal Investigator was appointed until the position is filled.
Discussion: None
Description of Action: Agreed

Study#: 40144
Title of Study: Project Connect: Evaluation of Public Health

Partnership to Prevent Violence Against Women
Principal Investigator: Elizabeth Miller, MD, PhD
Description: Providing clients (18 years or older) with option to complete the survey via email. (This option will not be available to minors due to risk for for breaches of confidentiality). Increasing the remuneration from $15.00 to $30.00 for clients completing the Time 2 survey.
Discussion: None
Description of Action: Agreed

Study#: 40145
Title of Study: Medullary Thyroid Carcinoma Surveillance Study: A Case Series Registry
Principal Investigator: Gretchen S. Dieck, PhD
Description: Some of the study patients may require materials in Spanish including the following: Spanish MTC Registry Patient Letter and Translation Certificate, Spanish MTC Registry Patient Brochure and Translation Certificate; Spanish MTC Registry Medical Release Authorization and Translation Certificate.
Discussion: None
Description of Action: Agreed

Study#: 40147
Title of Study: Assisted Reproductive Technology & Risk of Childhood Cancer
Principal Investigator: Barbara Luke, ScD, MPH, PhD
Description: A revision to the protocol, such that for each delivery conceived by Assisted Reproductive Technology (ART), the investigator will be asking for the subsequent 10 deliveries be selected to contribute to the comparison cohort. Protocol revision includes changes to Venn diagram, and clarification to the matching process and variables request to address the above modification.
Discussion: None
Description of Action: Agreed

Study#: 50122
Title of Study: Assessment for Reproductive Coercion at Domestic Violence Program Intake
Principal Investigator: Laura Crawford
Description: Expand the reproductive coercion assessment to four additional shelter pilot sites: The Laurel Center (Winchester, VA), Transitions Family Violence Services (Hampton, VA), Empower House (Fredericksburg, VA), Women's Resource Center of the New River Valley (Radford, VA).
Discussion: None
Description of Action: Agreed

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

Description: The study will begin with a minimum of eight health districts in hopes of having sufficient participants, otherwise the Principal Investigator (PI) will add more. The webinar on male reproductive health is being eliminated; packet contains a quiz on male reproductive health, knowledge, demographic information of participants and a list of challenges to implementing male reproductive health. The PI may not be collecting all the data; if the PI is not available to collect data on the day of the staff meeting, the nurse manager or designee will collect the data.

Discussion: None

Description of Action: Agreed

Meeting adjourned @ 12:48

Virginia Department of Health
Institutional Review Board
May 21, 2013
Minutes

Members Present: Chair Dev Nair, Bethany Geldmaker, Cecilia Barbosa, Ana Colon (via PolyCom), and Ronnette Langehorne (via PolyCom)

Members Absent: Jeffrey Stover

Staff Present: Janice Hicks

General Items/Announcements

- Meeting was convened at 1:10 PM. A quorum was confirmed.
- Minutes from January 7, 2013 meeting were reviewed and approved.
- Meeting schedule for the remainder of 2013
  - **July 8**
  - **October 7**

PRESENTATION OF NEW PROTOCOLS- EXEMPTION REVIEWS:

Study#: 50138
Title of Study: Cancer Survival in Appalachia
Principal Investigator: Bin Huang, DrPH
Primary Reviewer: Elisha Burke
Date Approved: January 9, 2013
Description: This is a multi-state study of cancer survival in West Virginia and portions of 12 Appalachian states including Virginia. Cancer registry data will be linked with National Death Index (NDI) data to determine factors that impact cancer survival rates. The Virginia Cancer Registry data will be a part of this study. The study uses existing data and the subjects will not be identified. All data transferred between agencies will be encrypted.
Description of Action: Agreed

Study#: 50139
Title of Study: Behavioral Health Integrated Centralized Intake: Assessing Provider Readiness and Perceptions of Behavioral Health Risk Screening
Principal Investigator: Sarah Kye Price, PhD, MSW
Primary Reviewer: Ana Colon
Date Approved: January 16, 2013
Description: This is a part of a larger study approved by VCU IRB. The purpose of the study is to assess Virginia's home visitation providers to gather baseline data regarding their readiness, attitudes, knowledge, and experiences with perinatal depression and behavioral health risk screening. The data will be collected through a de-identified electronic survey. No risks to human subjects were identified. The de-identified data will be presented in

aggregate form. The electronic records will only be available to the PI and staff and access is password protected.
Description of Action: Agreed

Study#: 50140
Title of Study: Exposure-Response Analysis for North American Vinyl Chloride Workers
Principal Investigator: Kenneth Mundt, PhD
Primary Reviewer: Ana Colon
Date Approved: January 16, 2013
Description: This study is an update of a retrospective cohort study of 10,109 male employees who worked at any North American Vinyl Chloride factories between 1942-1972 to determine the relationship between vinyl chloride exposure and causes of death – specifically causes combined with cancers, site-specific cancers and various non-malignant causes of death. Existing data will include the Epidemiological Research Database of the Social Security Administration, the National Death Index and death certificates. Confidentiality of identifiable information will be protected with passwords and restricted access. Identifiable data will also be separate from other project files and hard copy files will be stored in locked cabinets. Findings from the research will be presented in aggregate format.
Description of Action: Agreed

Study#: 50141
Title of Study: Rabies Post-Exposure Prophylaxis Epidemiology in Fairfax County, 2010
Principal Investigator: Steven Rekant, DVM Student
Primary Reviewer: Ronnette C. Langhorne
Date Approved: January 31, 2013
Description: The purpose of the study is to review and analyze data previously collected for public health purposes by the Fairfax County Health Department regarding Rabies Post-Exposure Prophylaxis. The study is a case review of persons that were potentially exposed to Rabies. Information will be used as a guide for future education and outreach programs related to rabies exposure. No human subjects will be contacted, surveyed or actively used in the study. The database will be de-identified prior to sharing with the principal investigator.
Description of Action: Agreed

Study#: 50142
Title of Study: Exposure Reconstruction and Updated Mortality Analysis for the US Industry-Wide Carbon Black Mortality Cohort Study
Principal Investigator: Kenneth Mundt, PhD
Primary Reviewer: Cecilia E. Barbosa
Date Approved: January 31, 2013
Description: This follow-up study will examine mortality patterns from lung cancer, non-malignant respiratory diseases, and cardiovascular diseases of employees of carbon black production facilities. The secondary data will come from death certificates and the National Death Index (NDI) database. No more than minimal risk. The study was previously

approved by ENVIRON IRB. Adequate security such as personal identifiers kept in secure, password- protected database and a data destruction plan is in place.
Description of Action: Agreed

Study#: 50143
Title of Study: Behavioral Risk Factor Surveillance System (BRFSS)
Principal Investigator: Danielle Henderson
Primary Reviewer: Ronnette Langhorne & Bethany Geldmaker
Date Approved: February 14, 2013
Description: The BRFSS is a CDC -funded cross-sectional telephone survey of adults that collects information on health risk behaviors, preventive health practices, and health care access primarily related to chronic disease an injury. The questionnaire is comprised of core questions and optional modules that have been approved through the CDC IRB along with the methods. Virginia is including 3 state-added series of questions regarding cognitive impairment, oral health and disability. Data sets do not contain any personal identifying data and data are aggregated. No identified risk to human subjects.
Description of Action: Agreed

Study#: 50144
Title of Study: Alexandria Redevelopment Housing Authority (ARHA) Healthy Air Study
Principal Investigator: Stephen A. Haering, MD, MPH, FACPM
Primary Reviewer: Bethany Geldmaker
Date Approved: February 15, 2013
Description: The purpose of the study is to measure the ARHA residents' exposure to and attitudes about environmental tobacco smoke, specifically with regard to how they might feel about living in smoke-free buildings. Surveys will be administered to a systematic-random sample of residents by trained interviewers. Verbal consent will be obtained before participation and information regarding the survey will be available. The project presents less than minimal risk to participants. Participation is voluntary and anonymous. Participants may skip any question and no identifying information will be collected.
Description of Action: Agreed

PRESENTATION OF NEW PROTOCOLS-EXPEDITED REVIEWS:

Study#: 40162
Title of Study: Pop-Out Effect in Infants
Principal Investigator: Krisztina Jakobsen, PhD
Primary Reviewer: Ana Colon
Date Approved: January 15, 2013
Description: This project was discussed and approved at the January 7, 2013 meeting.
Description of Action: None – previously approved
Study#: 40165

Title of Study: Spatial and Psychosocial Influences on Food Access in Rural Appalachia
Principal Investigator: Esther Thatcher, PhD, MSN, RN
Primary Reviewer: Ronnette Langhorne
Date Approved: January 23, 2013
Description: The purpose of this study is to describe some important influences on food access and food choices in low-income rural Appalachian residents. Participants will be recruited through the Lee County Head Start and the Health Department. The proposed study includes a very detailed informed consent documents. Data will be collected through interviews and in-store surveys of available food products. Procedures are in place to protect the identity of the participants including the storage of all code-identified participant study data in a separate location. Electronic files will be stored on a password-protected computer and double-entered into password-protected files. This study presents low risk to the participants.
Description of Action: Agreed

Study#; 40166
Title of Study: My Health Counts Population Health Study
Principal Investigator: Joseph P. McConnell, PhD
Primary Reviewer; Bethany Geldmaker
Date Approved: January 23, 2013
Description: This study is proposed to evaluate the health benefits of 6 months participation in HDL's Wellness Program. The study population will be recruited from VDH employees with COVA Care insurance. A detailed informed consent is included. The study includes a health screening through an online survey, advanced lab testing with a report provided to participant, an offer for services to better understand personal risk factors and improve health, and follow-up testing to track and measure improvement. If information is published, the subject's identity will remain confidential. Adequate procedures are in place for handling significantly abnormal lab values that are deemed to be life-threatening. (IRB Chair reported that VDH upper management has decided that VDH will not participate in this study.)
Description of Action: Agreed

Study#: 40167
Title of Study: Farmer's Market Subsidies as a Means to Improve Fruit and Vegetables Consumption among Low-Income Pregnant Women Acceptability and Feasibility
Principal Investigator: Audra Gollenberg, PhD
Primary Reviewer: Bethany Geldmaker
Date Approved: January 23, 2013
Description: The project will assess the effect of a targeted farmers' market subsidy program for pregnant women participating in the WIC program in the Lord Fairfax Health District in order to better understand the acceptance/satisfaction with the program and the attitudes towards eating fresh fruits and vegetables. The voluntary participants will complete a questionnaire and will receive a $20 pre-paid voucher to be used at the Farmer's Market. At the next WIC meeting the participants will complete a follow-up questionnaire and will receive an additional $10 voucher. All information provided by participants will be kept confidential and only be used for the purposes of the study. In order to link the study questionnaires with the

vouchers and WIC forms it will be necessary to collect some identifying information. Once all forms are linked, the identifying information will be removed. Hard copy questionnaires will be kept in a locked cabinet and the electronic information will be de-identified.
Description of Action: Agreed

Study#: 40168
Title of Study: Behavioral Health Integrated Centralized Intake in Virginia: Measuring Program and Community Impact
Principal Investigator: Sarah Kye Price, PhD, MSW
Primary Reviewer: Bethany Geldmaker
Date Approved: February 14, 2013
Description: This is a statewide program evaluation to determine to what extent the expansion of the centralized intake process, incorporating High Risk Behavioral Health Screening, improves access to home visiting services, recognition of and response to psychosocial risk compounding maternal and child health and community service linkage for women determined to be at elevated psychosocial risk. The research involves de-identified data and is largely a program evaluation, however it was submitted for expedited review because of the sensitive nature of data (mental health, substance abuse, interpersonal violence) in an at-risk population (pregnant women). A request for waiver of informed consent and the HIPAA process was requested and has been previously approved by the Virginia Commonwealth University (VCU) IRB. The same request is submitted to the VDH IRB. The researchers have taken precautions to de-identify the data in order to maximize the privacy of women who receive services. Asking women to sign informed consent would reveal their identities to the research team and may put them at more risk. Adequate protections are in place to minimize the risk to the participants.
Description of Action: Agreed

Study#: 40169
Title of Study: Implementation of Behavioral Health Integrated Centralized Intake in Virginia: Process and Outcomes of a Statewide MCHIEV Expansion Project
Principal Investigator: Sarah Kye Price, PhD, MSW
Primary Reviewer: Bethany Geldmaker
Date Approved: February 14, 2013
Description: The purpose of the study is to better understand the process of implementing behavioral health integrated centralized intake in Virginia's maternal and child health home visiting programs. The study population includes employees of MCHIEV home visitation programs, community professionals working with pregnant and post-partum women as well as pregnant and post partum women themselves. Written individual informed consent will be required from each participant. Baseline interviews will be conducted within the communities under consideration for expansion. Formative and outcome evaluation case studies will be generated within the study groups (new, augmented and usual care). Program participant stakeholders will be randomly selected. This study involves minimal risk to participants in that the interviews pertain to the implementation process. Adequate procedures are in place to maintain the confidentiality of the data.
Description of Action: Agreed

Study#: 40170
Title of Study: Improving Nutrition Knowledge in WIC Participants through "Health Bites"
Principal Investigator: Cynthia Rubenstein, PhD, RN, CPNP-PC
Primary Reviewer: Ana Colon
Date Approved: February 19, 2013
Description: The purpose of the study is to evaluate the self-efficacy and general nutrition knowledge of WIC participants completing the online "Health Bites" nutrition modules. All WIC participants are required to complete nutrition education at specified time periods to qualify for their WIC financial support. Participants can complete the requirement on line through "Health Bites" or through face-to-face/group educational sessions. The "Health Bites" modules include a pretest and posttest. The study objective is to compare pretest and posttest measures of self-efficacy and basic knowledge specific to the module that the WIC participant has selected. The grant funding for "Health Bites" requires an evaluation of the effectiveness of the intervention through an analysis of pretest and posttest. The purposed research project fulfills this requirement. The pretest/posttest analysis will be completed on a sampling of modules that have a minimum number (n=50) of participants completing them. The only identification will be a WIC Family ID number. The researchers will not have access to the WIC Family ID number or any demographic data. There is no additional risk for participants. Consent is not required since nutrition education is a WIC requirement and choosing to obtain credit for nutrition education through "Health Bites" is voluntary.

IRB members raised the question of whether the participants should be advised that the information will be used for research/evaluation. After discussion, it was decided that this is an area that could use some additional research to determine if there is any guidance on this issue. Members agreed that the study has minimal risk to the participants.
Description of Action: Agreed

Study#: 40171
Title of Study: The Behavioral Impact of Poor Birth Outcomes on Subsequent Pregnancies: A Study of Virginia PRAMS 2007-2010
Principal Investigator: Sara Varner, BA, (MPH Candidate)
Primary Reviewer: Cecilia E. Barbosa
Date Approved: February 19, 2013
Description: The purpose of this study is to examine cigarette smoking and alcohol use among pregnant women with a previous live birth with poor outcomes (low weight birth or preterm) compared to women with previous normal (full term or adequate birth weight) birth outcomes. The study uses secondary data from the Pregnancy Risk Assessment Monitoring System (PRAMS) and the birth certificate. There will be no direct interaction with research participants. No identifying data will be used in the analysis. Data will be password-protected and stored in locked rooms. At the end of the study the researchers' datasets will be destroyed and the original data will be returned to VDH.
Description of Action: Agreed

Study#: 40172
Title of Study: Infant Feeding Practices and Beliefs of Latina Mothers

Principal Investigator: Suzanne Ameringer, PhD, RN
Primary Reviewer: Ana Colon
Date Approved: March 7, 2013
Description: The purpose of this research is to explore the factors that contribute to Latina mothers overfeeding practices and to what extend these feeding practices are determined by the socioeconomic context and cultural traditions with the family. A sample of 90 immigrant low-income Latin origin mothers and their infants will be recruited from the Child Development Resources of Williamsburg and the Peninsula WIC offices. Half the sample will be mothers with infants whose weight is ≤ 85 percentile and half the sample will be mothers with infants whose weight is ≥ 85 percentile. Interviews will be conducted using a 70 page instrument. Written informed consent is required however participants with low literacy will have an opportunity to receive oral consent and sign it with a witness. Provisions are adequate for the protection of the participant's identity. Data will be kept in a locked file cabinet.
Description of Action: Agreed

Study#: 40173
Title of Study: The American Cancer Society Cancer Prevention Study-3 Registry Linkage
Principal Investigator: Alpa V. Patel, PhD
Primary Reviewer: Ronnette Langhorne
Date Approved: March 18, 2013
Description: The purpose of this study is to link participants in a large prospective nationwide study (Cancer Prevention Study-3) with the state cancer registry data in order to identify incident cancers and obtain diagnostic and prognostic information necessary to conduct epidemiologic analyses related to cancer. This national study is expected to include 300,000 men and women ages 30-65 with no history of cancer. The participants will provide informed consent, a waist measurement, and a blood sample and complete a brief questionnaire. Additional questionnaires will be completed periodically. The participants will be followed for at least 20 years. The data linkage project will involve a dataset of current study enrollees securely transferred to the Virginia Cancer Registry for a probabilistic match to determine cancer incidents. Provisions are adequate for the protection of the participant's identity. Data files that include identifiers necessary for follow-up are only accessible to select Study Management Group staff involved in these activities. Data files are password protected and all paper documents containing identifiers are shredded except those needed for later use. All documents are contained in a locked document room with limited staff access.
Description of Action: Agreed

PRESENTATION OF NEW PROTOCOLS—FULL BOARD REVIEW:
Study#: 40161
Title of Study: Motivational Interviewing Integrated with Social Network Counseling for Teens
Principal Investigator: Michael Mason, PhD
Description: This project was reviewed at a full IRB meeting on October 24, 2012 and was unanimously approved at the January 7, 2013 IRB meeting.
Description of Action: 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:	Agreed

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:	None
Description of Action:	Agreed

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:	Agreed

Study#;	40075
Title of Study:	Improving Capture of Chemotherapy Information Using Physician Office Billing
Principal Investigator:	Lynne Penberthy, MD, MPH
Discussion:	None
Description of Action:	Agreed

Study#:	40076
Title of Study:	Black Women's Health Study: A Follow-Up Study
Principal Investigator:	Lynn Rosenberg, ScD
Discussion:	None
Description of Action:	Agreed

Study#:	40087
Title of Study:	Richmond Region WIC Oral Health Intervention
Principal Investigator:	Susan Pharr
Discussion:	None
Description of Action:	Agreed

Study#: 40093 ©
Title of Study: Baby Basics (transitioned to study# 40107 Baby Basic Moms Club)
Principal Investigator: Merry McKenna
Discussion: None – transitioned to Study # 40107
Description of Action: Agreed

Study#: 40105 ©
Title of Study: Virginia Comprehensive Cancer Control Project
Principal Investigator: Jean Gaare Eby, ScD
Discussion: None
Description of Action: Agreed

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

Study#; 40107
Title of Study: Baby Basic Moms Club
Principal Investigator: Merry McKenna
Discussion: None
Description of Action: Agreed

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: Agreed

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

Study#: 40110
Title of Study: Improving the Management of Tuberculosis in Patients from Virginia Using a Whole-Blood Bactericidal Assay
Principal Investigator: Scott Heysell, MD
Discussion: None
Description of Action: Agreed

Study#; 40126 ©
Title of Study: WIC Program Assessment

Principal Investigator: Mary Beth Dunkenberger
Discussion: None
Description of Action: Agreed

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: Agreed

Study#: 40145
Title of Study: Medullary Thyroid Carcinoma Surveillance Study: A Case-Series Registry
Principal Investigator: Gretchen S. Dieck, PhD
Discussion: None
Description of Action: Agreed

Study#: 40146 (M)
Title of Study: Continued Follow-Up of PLCO Participants
Principal Investigator: Kelly J. Yu, PhD, MPH
Discussion: None
Description of Action: Agreed

Study#: 40147
Title of Study: Assisted Reproductive Technology & the Risk of Childhood Cancer
Principal Investigator: Barbara Luke, ScD, MPH
Discussion: None
Description of Action: Agreed

Study#: 40148 ©
Title of Study: Central Virginia STI Recidivism Risk Factors
Principal Investigator: Jane Emerson, RN
Discussion: None
Description of Action: Agreed

Study#: 40149 ©
Title of Study: Early Intervention Services for Children Who Are Deaf or Hard of Hearing
Principal Investigator: Parthenia Dinora, PhD
Discussion: None
Description of Action: Agreed

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
Discussion: The project is closed. The research was not conducted.
Description of Action: Agreed

© Closed
(M) Modified

OTHER (MINOR MODIFICATIONS, ETC):

Study#; 40146
Title of Study: Continued Follow-Up of PLCO Participants
Principal Investigator: Kelly J. Yu, PhD, MPH
Description: The replacement of the Supplemental Questionnaire (SQX) with the Medication Use Questionnaire (MUQ). The MUQ asks participants to provide consent to use their personal information obtained during the screening portion of the trial and updated as needed on the Annual Study Update Form, to attain health information from electronic records such as Medicare and Medicaid. The health information obtained from the electronic records will become part of the aggregate analytical dataset and will be used to address the study specific aims which do not include research into possible etiology of health conditions other than cancer. Replacing the SQX with the MUQ does not affect the risk level of the study.
Discussion: None
Description of Action: Agreed

Study#: 40156
Title of Study: Promising Practice Research & Evaluation: Virginia Resource Mothers Program
Principal Investigator: Linda Bullock, PhD, RN, FAAN
Description: The approved consent forms that are in English have been transcribed in Spanish and the University of Virginia Institutional Review Board has approved the changes.
Discussion: None
Description of Action: Agreed

Study#: 50133
Title of Study: Alcohol-Attributable Deaths and Rates by Selected Characteristics, Selected States, US, 2005-2009
Principal Investigator: Danielle Henderson, MPH
Description: This study will be analyzing alcohol-related deaths from 2006-2010 instead of 2005-2009.
Discussion: None
Description of Action: Agreed

General Discussion: The VDH IRB does not currently have a specific form or way of showing approval of the waiver of consent. The request for a waiver of consent happens rarely and often when it does happen another IRB is involved. Options to be considered at a future meeting include developing a specific form to send along with the approval letter that indicates that the VDH IRB has approved the waiver of consent or adding specific language to approval letters stating that the request for waiver of consent has been reviewed and approved.

The VDH IRB reviews informed consent forms and material provided to participants; however we do not provide any specific approval stamp or signature on the informed consent form that shows that it has been approved. The VDH IRB may want to consider adding an approval signature on the informed consent form.

Currently the required final summary report from completed research projects is not shared with all IRB members and not available to the public. Staff will research how we may add this to the IRB web site.

Meeting Adjourned at 2:55 PM

VIRGINIA DEPARTMENT OF HEALTH
INSTITUTIONAL REVIEW BOARD
JULY 8, 2013
MINUTES

Members Present: Chair Dev Nair, Bethany Geldmaker, Ana Colon, Ronnette Langhorne, Jeffrey Stover

Absent Member: Cecilia Barbosa

Staff Present: Tywanda Bolden, Janice Hicks

General Items/Announcements

- The meeting was convened at 10:15. A quorum was present.
- Minutes from May 21, 2013 meeting were unanimously approved.
- Revisions to the Human Subject Research Regulations were approved by the Board of Health at the June 6th meeting and are currently under review by the Office of the Attorney General.
- Recruitment of new members, alternate members, and expert consultants.
- Future meeting schedule:
  - **October 7, 2013**
  - **January 6, 2014**
  - **April 7, 2014**
  - **July 14, 2014**
  - **October 6, 2014**

PRESENTATION OF NEW PROTOCOLS-EXEMPTION REVIEWS:

Study #: 50145
Title of Study: Every Woman's Life-Is it Really an Early Detection Program?
Principal Investigator: Melanie Dempsey
Primary Reviewer: Ana Colon
Date Approved: April 10, 2013
Description: This study will analyze data from the Every Woman's Life (EWL) program to investigate/analyze the profile of women enrolled in the program for evidence and trends in early detection and the establishment of a medical home. The analysis will provide information regarding the differences between EWL women and those not served by the program. The study will use existing EWL data, documents, records and specimens. No informed consent is needed. EWL data is maintained in software provided by the Centers for Disease Control and Prevention (CDC). Individuals will not be identified directly or indirectly.
Description of Action: Agreed

Study #: 50146
Title of Study: Birth Certificate and Fetal Death Certificate Data Matching for the Post-Licensure Rapid Immunization Safety Monitoring Program (PRISM)

Principal Investigator: Nandini Selvam, PhD, MPH
Primary Review: Ana Colon
Date Approved: April 18, 2013
Description: Multi-state project funded by US Federal Drug Administration (FDA) to evaluate linkage rates for mothers and infants identified using health plan data and linkage rate of health plan data to birth and fetal death certificate data; to describe characteristics and birth outcomes of population of mothers and infants identified for vaccine safety surveillance through the Mini-Sentinel Post-Licensure Rapid Immunization Safety Monitoring (PRISM) system; to evaluate patterns and trends in vaccine and medication use during pregnancy and birth outcomes as a component of safety surveillance activities of the Mini-Sentinel Program; to evaluate the association between specific vaccines used during pregnancy and birth outcomes. Approximately 75,000 Virginia births are in their administrative claims data between 2004 and 2011. No informed consent necessary, secondary data used throughout the study. Data security is adequate. All the data will be incorporated as part of an on-going and continuous immunization safety monitoring program in pregnant women.
Description of Action: Agreed

Study#: 50147
Title of Study: Epidemiologic Study of One Million U.S. Radiation Workers
Principal Investigator: Michael Mumma
Primary Reviewer: Bethany Geldmaker
Date Approved: April 26, 2013
Description: This study will provide an evaluation of possible risks associated with low-dose radiation exposures over a prolonged period of time. The proposal includes linkage with Virginia Vital Statistics computer files to identify additional deaths among one million early radiation workers not identifiable through linkages with the Social Security Administration Master Death file to obtain the cause of death for these workers. All computer data files will be stored on password protected computers in a locked office. Personal information will be excluded from data analysis file to ensure confidentiality of the study participants. No publication or presented statistical tabulation will contain names or other personal characteristics that would enable identification of the study subjects. Aggregate data will be used in reports and tables.
Description of Action: Agreed

Study#: 50148
Title of Study: Health System Delivery Factors Associated with Influenza Vaccination Coverage during the H1N1 2009-10 Pandemic Response in Virginia
Principal Investigator: Brittany L. Foster (under the supervision of Dr. Robert D. Bradshaw)
Primary Reviewer: Ronnette Langhorne
Date Approved: May 14, 2013
Description: This is a VDH study of influenza vaccination data in localities to determine coverage rates for school age children and the methods used to deliver the

vaccinations. No informed consent is required; using existing data. Identifying information will not be used and all data is stored with password protection.
Description of Action: Agreed

Study#: 50149
Title of Study: Community Assessment for Public Health Emergency Response (CASPER) in Portsmouth Health District
Principal Investigator: Katie Kurkjian, DVM, MPH
Primary Reviewer: Bethany Geldmaker
Date Approved: May 16, 2013
Description: Epidemiologic methods will be used to collect household level information for community health assessment. Households will be randomly selected based on a sample of Census blocks. Following informed consent, respondents (age 18 years or older) will be interviewed regarding health assessment. All data will be stored and secured in accordance with the VDH Confidentiality Policy. Data will be analyzed primarily using ArcGIS software. A final report will be distributed to stakeholders along with training and questionnaire materials that can be used by other jurisdictions interested in performing this kind of assessment. There is minimal risk to the subjects.
Description of Action: Agreed

Study#: 50150
Title of Study: Comparison of Risk Factors Associated with Unilateral and Bilateral Hearing Loss Identified by Newborn Hearing Screening
Principal Investigator: Kelly M. Dodson, MD
Primary Reviewer: Ana Colon
Date Approved: June 6, 2013
Description: This is a retrospective review of children with confirmed hearing loss identified through Virginia's universal newborn hearing screening program from 2002-2008. Outcomes of interest are subjects with unilateral and bilateral hearing loss and the presence or absence of risk factors and co-occurring birth defects. Aggregate data summary tables will be prepared by VDH staff. The tables will be used by the research team to prepare a manuscript for publication in a peer-reviewed journal in collaboration with VDH staff. No risks to subjects are identified.
Description of Action: Agreed

PRESENTATION OF NEW PROTOCOLS –EXPEDITED REVIEWS:

Study#: 40175
Title of Study: Evaluating Effectiveness of a Third Dose of Measles-Mumps-Rubella (MMR) Vaccine for Mumps Outbreak Control, Henrico County and Richmond City, Virginia
Principal Investigator: Laura Ann Nicolai, MPH
Primary Reviewer: Bethany Geldmaker
Date Approved: April 10, 2013

Description: This is a VDH study to determine the effectiveness of a third dose of measles-mumps-rubella (MMR) vaccine in controlling a university-based outbreak of mumps. The vaccine will be offered to the students and followed by a survey 2 to 3 months later to determine the effectiveness of the third MMR vaccination. The consent form includes a separate section requesting permission for VDH to verify previous vaccination history with the University Student Health Center. All physical and electronic data will be stored in compliance with VDH Policy in a locked file cabinet with limited access to staff. All publications/reports will comply with VDH procedures on aggregate data release to ensure that individuals cannot be identified. The study poses minimal risk to the subjects.
Description of Action: Agreed

CONTINUATION/REVIEWS/RENEWALS:

Study#: 40027
Title of Study: Cross Cultural Infant Care Practices in Virginia
Principal Investigator: Fern Hauck, MD, MS
Discussion: None
Description of Action: Agreed

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

Study#: 40052
Title of Study: Follow-Up Study for Cancer Incidence for the Southern Community Cohort Study
Principal Investigator: William J. Blot, PhD
Discussion: None
Description of Action: Agreed

Study#: 40089
Title of Study: Hampton Roads VDH/VIMS Clam Studies
Principal Investigator: Howard Kator, PhD
Discussion: None
Description of Action: Study completed and closed.

Study#: 40092
Title of Study: Flight Attendants Health Study: The Incidence of Breast and Other Cancer Among Female Flight Attendants
Principal Investigator: Lynne E. Pinkerton, MD, MPH
Discussion: None
Description of Action: Agreed

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 Prezant, MD
Discussion: None
Description of Action: Agreed

Title#: 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: Agreed

Title#: 40132
Title of Study: Smoking Cessation during Pregnancy
Principal Investigator: Linda Bullock
Discussion: None
Description of Action: Summary provided and closed.

Title#: 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: Study completed and closed.

Title#; 40134
Title of Study: Linkage of Virginia Cancer Registry for an Ongoing Retrospective Cohort Study for Satellite Workers
Principal Investigator: Joseph K. McLaughlin, PhD
Discussion: None
Description of Action: Publication provided and closed.

Title#: 40150
Title of Study: 2012 Virginia Statewide Oral Health Needs Assessment of Sentinel Schools
Principal Investigator: R. Lynn Browder, DDS
Discussion: None
Description of Action: Agreed

Title#: 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
Discussion: None

Description of Action: Agreed

Study#: 40152
Title of Study: A Study of Rocky Mountain Spotted Fever Diagnosis in Health Districts in Virginia
Principal Investigator: Lisa Ferguson, RN, BSN
Discussion: Summary provided and closed.

Title#: 40153
Title of Study: The Women's Interagency HIV Study (WIHS)
Principal Investigator: Mary Young, MD
Discussion: None
Description of Action: Agreed

OTHER (MINOR MODIFICATIONS, ETC):

Study#: 40146
Title of study: Continued Follow-Up of PLCO Participants
Principal Investigator: Kelly J. Yu, PhD, MPH
Description: A second data linkage containing the same variables as those included in the approved protocol is requested. As in the approved protocol, this second data linkage should include all cancers at all sites including benign brain tumors diagnosed between 1993 and 2010. The approved protocol is a follow-up of the cohort of men and women who participated in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screen Trail. The reason for this request is some of the participants who were recruited and screened for the PLCO Cancer Screening Trail in Georgetown University (GTU) were erroneously not included in the data linkage input file that was submitted to the Virginia Cancer Registry as per the approved protocol. Due to the proximity of the GTU screening centers to Virginia all participants who were recruited and screened at GTU during the PLCO Cancer Screening Trail should have been included in the initial data linkage input file. Approximately 1,200 participants were accidentally left out of the initial data linkage input file. To correct this, a second linkage request is being submitted to the Virginia Cancer Registry.
Description of Action: Agreed

Study#: 40151
Title of Study: Preventing Cervical Cancer in Rural Women through Nursing Practiontioner Colposcopy Services: Ensuring Patient Safety and Effectiveness
Principal Investigator: Audrey E. Snyder, PhD, RN, ACNP-BC, FAANP
Description: The study Principal Investigator was changed from Elizabeth Merwin, PhD, to Audrey E. Snyder, PhD due to Dr. Merwin relocating out-of-state.
Description of Action: Agreed

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

Description: The request amends focus group recruitment criteria, the consent form and adds a demographic questionnaire. The request also submits documents in support of the quantitative phase of the mixed methods study on infant feeding: a survey, flyer and consent form. An amended research plan is submitted reflecting all changes. Changes to the focus group included amending one of the focus group recruitment criteria from six to twelve months of breastfeeding to at least four months of breastfeeding. The researchers indicate that the change was necessary in order to recruit more women for this group. An additional questionnaire was included to capture anonymous demographic and infant feeding practice information from focus group participants. The participants consent form was modified to reflect the latter change. The proposal was approved by the Virginia Commonwealth University Institutional Review Board (VCU IRB) on February 28, 2013. The original research plan stated that details on the quantitative phase (self-administered survey) would be submitted upon completion of the qualitative phase focus groups. Documents are attached in support of the quantitative phase, which involves recruitment of approximately 180 participants at the three Richmond City WIC sites to complete a 12 page self administered survey. The survey takes about 15-20 minutes to complete. The Richmond City Health District has approved the use of the WIC sites for recruitment. Richmond City Health District staff will not be engaged in this research. Provided documents include a survey, informed consent form and advertisements which has been revised and approved by the VCU IRB on May 30, 2013.

Description of Action: Agreed

Study#: 40165

Title of Study: Spatial and Psychosocial Influences on Food Access in Rural Appalachia

Principal Investigator: Esther Thatcher, PhD, MSN, RN

Description: Recruitment will be expanded from only working through two community agencies, to include snowball sampling and collaborating with a variety of community organizations that serve economically disadvantaged women such as churches, food banks and family-oriented social services. The rationale for this expansion is to increase services from food banks and other safety net organizations. Snowball sampling may succeed in reaching eligible participants who are not currently clients of community service agencies or organizations. A new interview procedure will be added: semi-structured interviews will be conducted with food store managers and safety net services personnel, such as ministers, social workers and food pantry operators. These interviews will focus only on the participants' job or volunteer roles, and will not ask questions about the participants' personal lives. These interviews will add a valuable source of data on the county's food systems, services for low-income residents and histories of past programs to promote healthy nutrition. Study timeframe is also extended.

Description of Action: Agreed

Study#: 50116

Title of Study: Alexandria Public Health and Safety Agencies Closed Point of Dispensing Trainings: Evaluating Attitudes Toward Medication Dispensed At a Closed Point of Dispensing

Principal Investigator: Stephen A. Haering, MD, MPH
Discussion: Changed the title of the study and expanded the study population to include additional public health and safety agencies in the City of Alexandria including police, sheriff and health department employees.
Description of Action: Agreed.

Study#: 50143
Title of Study: Behavioral Risk Factor Surveillance (BRFSS)
Principal Investigator: Danielle Henderson
Discussion: The modification request includes an additional method of contacting telephone non-respondents by a post card directing them to a website to complete the BRFSS questionnaire. The website does not collect any personal health information (PHI). All BRFSS data are reported in aggregate.
Description of Action: Agreed

Study#: 50144
Title of Study: Alexandria Redevelopment Housing Authority (ARHS) Healthy Air Study
Principal Investigator: Stephen A. Haering, MD, MPH, FACPM
Discussion: The timeline for data collection is extended to August 31. 2013.
Description of Action: Unanimously Approved.

Meeting adjourned @ 12:15 pm

VIRGINIA DEPARTMENT OF HEALTH
INSTITUTIONAL REVIEW BOARD
OCTOBER 8. 2013
MINUTES

MEMBERS PRESENT: Chair Dev Nair, Jeffrey Stover, Cecilia Barbosa, Ana Colon (via Poly-Com) and Ronnette Langhorne (via Poly-Com).
Absent Member: Bethany Geldmaker
Staff Present: Janice Hicks and Tywanda Bolden

Guest: Emily McClellan, Survey and Analysis Unit Manager, OFHS Policy and Evaluation Division

General Items/Announcements: Draft copies of updated forms were distributed for member review. Dr. Nair requested that members provide feedback to Janice Hicks within two weeks. Following general discussion of IRB processes, it was decided that any major modifications submitted by a Principal Investigator should be returned to the original reviewer for review. In addition, the need to make sure that PIs are aware of VDH's minor's policy was identified as well as the need to develop and share information on how to request data from VDH. Preliminary discussion began on how the IRB may be able to lessen the paperwork of proposals that have been previously reviewed by another IRB.

Scheduled Meetings for **2014**

- **January 6**
- **April 7**
- **July 14**
- **October 6**

PRESENTATION OF NEW PROTOCOLS-EXEMPTION REVIEWS:

Study#: 50151
Title of Study: Attitudes about Breast Cancer in Rural Appalachia
Principal Investigator: Santana VanDyke (Dr. Madelyn Shell, Advisor)
Primary Reviewer: Ana Colon
Date Approved: July 12, 2013
Description: The purpose of the study is to investigate health behaviors and attitudes such as breast cancer fears and general health concerns and the decision to get a mammogram. Data will be collected via survey at various health fairs during which mammograms will be available. The survey responses of women choosing to receive a mammogram and those choosing to not receive a mammogram will be compared. No identifying data will be collected.
Description of Action: Agreed

Study#: 50152
Title of Study: Evaluating Attitudes toward Disease Prevention Behaviors among Staff at Long-term Care Facilities and Schools in the City of

Alexandria
Principal Investigator: Stephen A. Haering, MD, MPH, FACPM
Primary Reviewer: Cecilia E. Barbosa
Date Approved: September 24, 2013
Description: The study will assess attitudes that staff at long-term care facilities and schools in Alexandria have toward disease prevention behaviors, such as seasonal flu vaccine, hand hygiene and cough etiquette. Online and paper surveys will be distributed to school and long-term care facility staff. Participation is voluntary and no identifiable information will be collected.
Description of Action: Agreed

PRESENTATION OF NEW PROTOCOLS-EXPEDITED REVIEWS:

Study#: 40176
Title of Study: Improving Access to Prenatal Care
Principal Investigator: Elizabeth D. Beasley, MPH
Primary Reviewer: Cecilia E. Barbosa
Date Approved: May 4, 2013
Description: The purpose of this study is to identify specific barriers to accessing prenatal care in the Thomas Jefferson Health District. The target population is mothers and pregnant women between 15 and 35 who reside in traditionally lower-income areas of Charlottesville, Nelson and Louisa counties. Participants will be recruited through flyers distributed in local health departments, community partner organizations, prenatal clinics and WIC clinics. Information collected during the focus groups and questionnaires includes attitudes and experiences regarding prenatal care providers, and patient levels of health knowledge of the importance of prenatal care. No identifiable information will be collected. Participating minors will be required to provide a signed parental consent form. No personal identifiable information is collected during the focus group. Recording and individual questionnaires will be destroyed after the report is written. Digital information will be stored in a password protected folder on a secure network drive.
Description of Action: Agreed

Study#: 40178
Title of Study: Talking Health-Main Trial
Principal Investigator: Jamie Zoellner, PhD, RD
Primary Reviewer: Ana Colon
Date Approved: July 12, 2013
Description: This is an 18 month randomized control intervention funded by NIH/NCI to decrease sugar -sweetened beverage intake among adults in eleven counties in Southwest Virginia. Participants must be 18 years of age or older, English speaking, non institutionalized and consuming more than 200 calories per day of sugar-sweetened beverages per day and be without medical conditions in which physical activity would be contraindicated. Recruitment will be via word of mouth, recruitment flyers, newspaper advertisements and community meetings. An oral consent statement will be read and signed consent will be obtained from each participant. Any potential participant having repeated measures of systolic

blood pressure at or above 160 or diastolic blood pressure at or above 100 will be required to obtain a medical release to participate. The intervention group will receive 3 nutrition education sessions focusing on reducing sugar-sweetened beverage consumption. The control group will receive 3 physical activity education sessions. Periodic telephone calls to both groups will document sugar-sweetened beverage consumption. Data will be maintained in a locked file cabinet. Plans include publishing summary/aggregate findings in a peer reviewed journal. Research staff has completed training in the protection of human subjects.
Description of Action: Agreed

Study#; 40179
Title of Study: Virginia Youth Survey
Principal Investigator: Danielle Henderson
Primary Reviewer: Bethany Geldmaker
Date Approved: July 31, 2013
Description: This is a nationally supported survey that monitors six categories of health-risk behaviors among youth, including behaviors that contribute to unintentional injuries and violence; tobacco use; alcohol and other drug use; unhealthy dietary behaviors; physical inactivity; obesity and asthma. The survey will be conducted in randomly selected middle and high schools. A parental consent form will be provided to parents with information regarding the survey and an option to opt out. Survey procedures are designed to protect student privacy. Participation will be voluntary and no identifying information will be collected. Scanning and analysis of the survey will be completed by Westat and the Centers for Disease Control. Once results are final, a press release will be developed informing parents, school officials and other interested parties that the results are available on the VDH website.
Description of Action: Agreed

Study#: 40180
Title of Study: Survey of the Food Environment in Lenowisco Health District, VA
Principal Investigator: Esther Thatcher, MSN, RN, PhDc
Primary Reviewer: Ronnette Langhorne
Date Approved: August 12, 2013
Discussion: The purpose of the study is to determine the availability and price of certain food items in the area. The data will be used to plan public health programs to improve nutrition in Southwest Virginia. A standardized instrument will be used to collect data from individual stores. The store manager will be informed of the study and request permission to collect data regarding the availability and price of items. Food store names and location information will be maintained in password protected file and/or a locked file drawer. De-identified data may be shared with other agencies for planning purposes.
Description of Action: Unanimously Approved

PRESENTATION OF NEW PROTOCOLS-FULL REVIEW:

Study#: 40181
Title of Study: The Effect of Urban Empowerment Zones of Health Outcomes
Principal Investigator: John Cawley, PhD
Discussion: A full board meeting was held on August 16, 2013. The minutes

are attached.
Description of Action: Unanimously Approved

CONTINUATION/REVIEWS/RENEWALS:

Study#: 40068
Title of Study: Medical Monitoring Project
Principal Investigator: Celestine Buyu
Discussion: None
Description of Action: Agreed

Study#: 40069
Title of Study: Virginia Pregnancy Risk Assessment Monitoring System (VA-PRAMS)
Principal Investigator: Derek Chapman, PhD
Discussion: None
Description of Action: Agreed

Study#: 40101
Title of Study: Cancer Epidemiology in Adventists
Principal Investigator: Gary E. Fraser
Discussion: None
Description of Action: Agreed

Study#: 40102
Title of Study: Analysis of Urethral Exudates in Acute Gonorrhea
Principal Investigator: Alison Criss, PhD
Discussion: None
Description of Action: Agreed

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

Study#: 40136
Title of Study: Social-spatial Risk and Protective Mechanisms in Urban Adolescent Substance Use
Discussion: None
Description of Action: Agreed

Study#: 40137

Title of Study: The Association Between Maternal Obesity and Adequacy of Prenatal Care
Principal Investigator: Saba Masho, MD, MPH, DrPH
Discussion: None
Description of Action: Agreed and Closed

Study#: 40140
Title of Study: Lord Fairfax Health Department Youth Risk Behavior Survey
Principal Investigator: Charles J. Devine, III, MD
Discussion: None
Description of Action: Agreed and Closed

Study#: 40154
Title of Study: Post-Marketing Surveillance of Adverse Effects of a New Treatment Regimen
Principal Investigator: Christine Ho, MD, MPH
Discussion: None
Description of Action: Agreed

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
Discussion: None
Description of Action: Agreed

Study#: 40158
Title of Study: Camp Lejeune Health Survey
Principal Investigator: Perri Ruckart, MPH
Discussion: None
Description of Action: Agreed

Study#: 40160
Title of Study: An Academic-Community Partnership to Address Health Disparities in Infant Mortality
Principal Investigator: Audra Gollenberg, PhD
Discussion: None
Description of Action: Agreed

Study#: 40177
Title of Study: Feasibility Study of Community Garden Projects to Improve Nutrition for WIC Clients
Principal Investigator: Janice Lorraine Taylor Peters
Discussion: None
Description of Action: Agreed and Closed, Summary Provided

Study#: 50128
Title of Study: Investigating the Relationship Between High School Students' Self Reports of Suicidality, Sad Feelings and Bullying Behavior
Principal Investigator: Heather Merner, M.A
Discussion: None
Description of Action: Agreed and Closed, Summary Provided

OTHER (MINOR MODIFICATIONS, ETC)

Study#: 40068
Title of Study: Medical Monitoring Project
Principal Investigator: Celestine Buyu
Discussion: The protocol, interview guide and questionnaire has been updated to reflect the new data collection cycle. The consent form has been updated to include Jacek Skarbinski's name, the national Principal Investigator and Division of HIV-AIDS Prevention (CDC) representative. The protocol and instruments have been updated to include new definitions and questions. The medical records abstraction software has been changed to a web based application.
Description of Action: Agreed

Study#: 40092
Title of Study: Flight Attendants Health Study: The Incidence of Breast and Other Cancer among Female Flight Attendants
Principal Investigator: Lynne E. Pinkerton, MD, MPH
Discussion: Add additional support staff for the analysis stage of the project.
Description of Action: Agreed

Study#: 40176
Title of Study: Improving Access to Prenatal Care
Principal Investigator: Elizabeth D. Beasley, MPH
Discussion: The age range of the target population for this study will be changed from 15 to 35 to 13 to 35 years since a number of currently pregnant 13 and 14 year olds currently receiving prenatal services are interested in participating. Minors will continue to need their parent/guardian's consent to participate. Expanding the age range does not impose any additional risk to the study participants. In addition, a new facilitator and report writer will be working on the study.
Description of Action: Agreed

Meeting adjourned @ 12:32

Virginia Department of Health
Institutional Review Board
August 16, 2013
Full Board Review Minutes

Members Present: Dev Nair, Jeffrey Stover, Cecilia Barbosa, Ana Colon (Polycom), Ronnette Langhorne (Polycom)
Members Absent: Bethany Geldmaker
Staff: Janice Hicks, Tywanda Bolden
Expert Consultants: Brendan Noggle and Kenneth Studer

Discussion: The Effect of Urban Empowerment Zones on Health Outcomes, a research proposal submitted by Daniel Grossman, Cornell University.

The full board met to obtain additional information from the principal investigator and consider the board's policies regarding studies that include geo-coded data. During the meeting, Daniel Grossman, the co-principal Investigator, was contacted by telephone and placed on speaker. Mr. Grossman provided the members with an overview of the study that will explore the effect of Empowerment Zones on the people living in the communities. The study includes the use of existing data sets (vital statistics, demographics, Census data and Dun and Bradstreet data) from all 50 states. Mr. Grossman responded to questions regarding data security and any potential confidentiality issues arising from small numbers. He provided information on data security including the restricted access to data. Mr. Grossman will be the only user that has access to the data. He also indicated that data will not be reported by individual Empowerment Zone, but as a whole which eliminates any issue with small numbers and the related potential confidentiality issues.

Mr. Grossman is requesting that states provide geo-coded vital statistics data for the Census tracts that make up the Empowerment Zones. Discussion centered on the availability of geo-coded data which may not be available through the VDH Health Statistics. The OFHS has geo-coded birth data; however OFHS is not authorized to release the data. VDH Health Statistics has Census level data. Further discussions focused on mechanisms that could be used to transfer the data to Cornell if it is approved for release by VDH Health Statistics.

Mr. Grossman agreed to provide a list of census tracts and provide a copy of the data agreement if his request is approved by VDH Health Statistics.

Following Mr. Grossman's phone conversation, members continued the discussion. Dr. Nair agreed to contact Calvin Reynolds and discuss any concerns that the board has including, if approved, how the data would be transferred and the possible release of data that includes identifying information (names, SSN, etc.). Also, Dr. Nair will determine if OFHS could be authorized to provide geo-coded data or if Health Statistics could release OFHS geo-coded data.

The board members unanimously agreed that the study had adequate data security and protections in place and agreed that the research proposal could be approved if de-identified

Census data is used pending additional info from Mr. Grossman and communication with Calvin Reynolds.

The meeting adjourned at 3:00 PM.