To: The Honorable Mark R. Warner, Governor
The General Assembly of Virginia

From: Robert B. Stroube, M.D., M.P.H.
State Health Commissioner

Date: February 9, 2005

Re: Annual Report of the Virginia Department of Health's Institutional Review Board

Enclosed please find a report entitled "Activities of the Virginia Department of Health's Institutional Review Board for Calendar Year 2004." This report is submitted pursuant to § 32.1-12.1 of the Code of Virginia and 12VAC5-20-50 of the Virginia Administrative Code. Should you have any questions concerning the report, please contact Joseph J. Hilbert, Executive Advisor to the Commissioner, at 864-7006.

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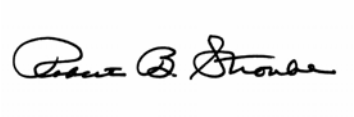
Sincerely,



Robert B. Stroube, M.D., M.P.H.
State Health Commissioner

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REPORT TO THE COMMISSIONER:

ACTIVITIES OF THE VIRGINIA DEPARTMENT OF HEALTH INSTITUTIONAL REVIEW BOARD FOR CALENDAR YEAR 2004

Submitted by

Kathy H. Wibberly, Ph.D.
Chair, Virginia Department of Health Institutional Review Board

REPORT TO THE COMMISSIONER:
ACTIVITIES OF THE VDH IRB FOR CALENDAR YEAR 2004

Regulations for the conduct of human research, developed and approved by the Board of Health, became effective on July 1, 1993. According to those regulations, prior to the initiation of a human research project by any institution or agency funded or licensed by the health department, a description of the proposed human research project shall be submitted to a research review committee for review and approval. The Virginia Department of Health (VDH) had been relying on the research review committees of academic institutions around the state; however, this precluded VDH's ability to conduct research that did not have a co-investigator at an academic institution. A committee was formed in the spring of 2000 to explore the viability of developing a research review committee (Institutional Review Board) here at VDH and a determination was made to proceed. Committee members were appointed and a policy document, *The Institutional Review Board (IRB) of the Virginia Department of Health (VDH): Guidelines and Procedures for Obtaining Review,* was developed and approved by the Commissioner in January 2001.

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

The following is a summary of the activities of the VDH IRB as per State regulations for the conduct of human research (12 VAC 5-20-10) during calendar year 2004.

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

A. Full Board Reviews

None

B. Expedited Reviews:

Study #:	**40032**
Principal Investigator:	Fred Angulo, DVM, Ph.D., Centers for Disease Control and Prevention, Foodborne and Diarrheal Diseases Branch
Title of Protocol:	"Interview of persons from which enteric bacterial isolates have been cultured with uncommon antimicrobial resistance patterns"
Date approved:	February 13, 2004
Description of Study:	This study interviews persons whose enteric bacterial isolates have shown uncommon antimicrobial resistance patterns in order to identify potential exposure factors and clinical consequences of infections associated with these uncommon resistance patterns.

Study #: **40033**
Principal Investigator: Casey Riley
Virginia Department of Health, Division of HIV/STD
Title of Protocol: "Antiretroviral Drug Resistance Testing (ARVDRT) in Individuals Newly Diagnosed with HIV"
Date approved: March 23, 2004
Description of Study: This project evaluates the feasibility and utility of incorporating baseline antiretroviral drug resistance testing in antiretroviral drug naive individuals newly diagnosed with HIV into routine HIV surveillance. Studies show that the prevalence of resistance strains is increasing among chronically infected treatment naive individuals, as well as those acutely infected. This study will help to better document if this is truly the case and provide evidence for the potential benefit of baseline testing to optimize clinical decision making.

Study #: **40034**
Principal Investigator: Casey Riley
Virginia Department of Health, Division of HIV/STD
Title of Protocol: "Estimating HIV Incidence by Using a Population-based Serologic Method to Detect Recent HIV-1 Infection"
Date approved: March 23, 2004
Description of Study: This study seeks to produce local area estimates of HIV and apply a statistical model to make national incidence estimates. This activity is part of a national CDC led HIV Incidence Project. VDH will be using a Serologic Testing Algorithm for Recent HIV Seroconversion (STARHS) technology to make more precise measurement of HIV incidence in Virginia.

Study #: **40035**
Principal Investigator: Beth Ehrensberger
Virginia Department of Health, Office of Family Health Services
Title of Protocol: "Listening to the Experts to Increase Cancer Screening in Virginia"
Date approved: April 12, 2004
Description of Study: This focus group study asks women about identifying factors (emotional and rational) that may encourage them to schedule and attend breast and cervical screening appointments.

Study #: **40036**
Principal Investigator: Ms. Tanya Bobo, MPH
Virginia Department of Health, Office of Epidemiology
Title of Protocol: "West Nile Virus Seroprevalence Study of Bird Handlers in Virginia"
Date approved: May 19, 2004
Description of Study: West Nile Virus (WNV), which had spread to 46 states by 2003, is typically carried by and transmitted between mosquitos and birds. The purpose of this study is to determine if bird handlers are at risk for acquiring WNV directly from handling wild birds; identify risk and protective factors, and determine if special precautions are needed to protect bird handlers.

Study #: **40037**
Principal Investigator: Gary M. Marsh, Ph.D.
University of Pittsburgh
Title of Protocol: "The Cohort Mortality and Cancer Incidence Studies of the Rahway, NJ Facility"
Date approved: July 12, 2004
Description of Study: This study investigates the mortality and cancer incidence among current and former employees of the Merck (Rahway, NJ) manufacturing facility.

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Study #: **40038**
Principal Investigator: H. Paul Brumund
Chesapeake Health Department
Title of Protocol: "US SARS-CoV Cases: Once Year Follow-up Study"
Date approved: August 17, 2004
Description of Study: This is a CDC lead study of laboratory confirmed SARS-CoV disease in nine U.S. citizens, one of whom is a Virginia resident. The major objectives of the study are to determine if lab-confirmed SARS-CoV patients have detectable antibodies to SARS-CoV one year or longer after infection and to obtain a unit of blood from those who demonstrate a high titer of antibodies for use in refinement and development of SARS diagnostic tests.

Study #: **40039**
Principal Investigator: Bridget J. McCarthy, Ph.D.
Title of Protocol: "Central Brain Tumor Registry of the United States (CBTRUS)"
University of Illinois at Chicago, School of Public Health
Date approved: July 5, 2004
Description of Study: This study will describe the epidemiology of all primary non-malignant and malignant brain and CNS tumors.

Study #: **40040**
Principal Investigator: Meir Stampfer, M.D., Dr. Ph.H.
Channing Laboratory, Brigham and Women's Hospital
Title of Protocol: "Cohort Cancer Registry Follow-Up Study"
Date approved: July 27, 2004
Description of Study: The purpose of this study is to use state cancer registry data from a number of states, including Virginia, in conjunction with previously collected data from three large scale prospective cohort studies to determine the specific causes of discrete types of cancer.

Study #: **40041**
Principal Investigator: Elizabeth Eustis-Turf, Ph.D.
Title of Protocol: "The Epidemiology of Human Rabies Postexposure Prophylaxis in Virginia"
VCU Department of Preventive Medicine and Community Health
Date approved: July 22, 2004
Description of Study: The purpose of this study is to evaluate the administration of human rabies postexposure prophylaxis (PEP) and offer recommendations on appropriate PEP administration to health care professionals and public health officials for policy development.

Study #: **40042**
Principal Investigator: Angela H. Taylor, M.P.A.
VCU Survey and Evaluation Research Laboratory
Title of Protocol: "An Assessment of Outcome Evaluation for the Virginia Department of Health's Adolescent Sexual Health Initiatives"
Date approved: July 30, 2004
Description of Study: This is a case study of two VDH initiatives related to adolescent sexual health. The purpose of the study is to provide guidelines to VDH regarding structural aspects of the two initiatives and to determine the factors that make an initiative a good candidate for outcome evaluation.

Study #: **40043**
Principal Investigator: Dr. Mitchell Holland
The Bode Technology Group
Title of Protocol: "Collection Procedures for DNA Identification of John/Jane Does"
Date approved: August 17, 2004
Description of Study: The purpose of this study is to examine sampling processes that would allow for optimal DNA profiling in order to assist medical examiner's offices with the identification or future identification of unidentified bodies.

Study #: **40044**
Principal Investigator: Allen N. Lewis, Ph.D.
VCU Survey and Evaluation Research Laboratory
Title of Protocol: "Reducing the Risk: City of Richmond Teen Pregnancy Prevention Initiative"
Date approved: October 29, 2004
Description of Study: The purpose of this study is to gather data about participant experiences in the Reducing the Risk program at City of Richmond high schools through focus groups and pre/post test surveys.

Study #: **40045**
Principal Investigator: Sarah Jane Brubaker, Ph.D.
VCU Survey and Evaluation Research Laboratory
Title of Protocol: "Evaluation of the Postponing Sexual Involvement Program"
Date approved: November 4, 2004
Description of Study: The purpose of this study is to evaluate the Postponing Sexual Involvement Program using a pre-post test program-only group design. Study participants will be 7th and 8th grades students enrolled in a community based teen pregnancy prevention program and/or alternative middle school.

Study #: **40046**
Principal Investigator: Allen N. Lewis, Ph.D.
VCU Survey and Evaluation Research Laboratory
Title of Protocol: "Passport to Manhood (PTM) Program Evaluation"
Date approved: October 18, 2004
Description of Study: The purpose of this study is to evaluate the Passport to Manhood (PTM) Program, a component of the Crater Health District Teen Pregnancy Prevention Initiative for youth ages 11 – 14. The evaluation employs pre- and post-test surveys.

Study #: **40047**
Principal Investigator: Tejpratap Tiwari, M.D**.**
Centers for Disease Control and Prevention
Title of Protocol: "Risk Factors for Mortality Due to Pertussis among Infants in the U.S. – A Case Control Study"
Date approved: November 29, 2004
Description of Study: This is a retrospective case-control study investigating the association of potential risk factors with fatal outcomes of pertussis (whooping cough) among infants younger than 12 months of age. It compares the characteristics of fatal cases of pertussis with those of non-fatal cases.

C. Exemption Reviews

Study #: **50013**
Principal Investigator: Gerges Seifen, M.D., MPH
Virginia Department of Health, Office of Family Health Services
Title of Protocol: "Behavioral Risk Factor Surveillance System State-Added Questions"
Date approved: January 5, 2004
Description of Study: The addition of 45 "state-added" questions to the CDC Behavioral Risk Factor Surveillance Survey master protocol. State added questions pertain to diabetes, dental health, motor vehicle safety, injuries due to falls, domestic violence, suicidal ideation, ADHD, women's health, antibiotic use, and cancer.

Study #: **50014**
Principal Investigator: Ramona Dawn Schaeffer, MSEd, CHES
Virginia Department of Health, Division of Chronic Disease Prevention
Title of Protocol: "Virginia Diabetes Primary Prevention Project"
Date approved: March 3, 2004
Description of Study: The purpose of project is to convene a group of people who can provide answers to questions related to developing successful diabetes primary prevention programs.

Study #: **50015**
Principal Investigator: Mary E. Rives, MPA
Title of Protocol: "CHSCN Part 1: Parental Satisfaction Survey"
VCU Survey and Evaluation Research Laboratory
Date approved: March 4, 2004
Description of Study: The purpose of project is to evaluate the Care Connection for Children (CCC) Program. The CCC program is designed to help parents of special needs children effectively navigate the healthcare system and receive necessary services for their children. The study uses a pre-post test survey design that assesses parental satisfaction with their access to and use of health care services before and after participating in CCC for one year.

Study #: **50016**
Principal Investigator: Marthe Bryant-Genevier, M.D., CBER
Center for Biologics Evaluation and Research, Food and Drug Administration
Title of Protocol: "Smallpox Immunization: Determinants of Acceptance"
Date approved: April 1, 2004
Description of Study: This study investigates the determinants of acceptance of smallpox vaccine among U.S. medical and public health personnel during Phase 1 of the 2003 Pre-Event Smallpox Vaccination Campaign. The study is a cross-sectional analysis of a sample of Health Care Personnel comparing factors that could have influenced the decision to accept or refuse the voluntary smallpox vaccination between vaccines and non-vaccinees. Data will be collected via a self-administered anonymous confidential questionnaire.

Study #: **50017**
Principal Investigator: Mary Padgett, R.N.
Chesterfield Health Department
Title of Protocol: "Needs Assessment for My Choice My Future Program"
Date approved: June 24, 2004
Description of Study: This is a needs assessment involving an anonymous survey of individuals on teen pregnancy prevention and Family Life Education. The purpose of the study is to determine the perceptions of two communities in relation to teen pregnancy prevention and Family Life Education.

Study #: **50018**
Principal Investigator: Howard J. Martin
Virginia Department of Health, Virginia Cancer Registry
Title of Protocol: "National Program of Cancer Registries/Virginia Cancer Registry – Indian Health Services Record Linkage"
Date approved: July 12, 2004
Description of Study: This goal of this study is to identify patients in the Virginia Cancer Registry (VCR) who are racially American Indian or Alaskan native but for whom the VCR does not have race information or for whom the information it does have classifies the patients as not American Indian or Alaskan Native. Databases from the Indian Health Services will be linked to the VCR in order to enhance the completeness and quality of cancer surveillance data in the Virginia cancer registry database.

Study #: **50019**
Principal Investigator: Susan Kennedy Spain
VCU Survey and Evaluation Research Laboratory
Title of Protocol: "CHSCN Part 2: Parental Satisfaction Survey of CCC Participants"
Date approved: October 4, 2004
Description of Study: The purpose of this study is to evaluate the Care Connection for Children (CCC) program by surveying parents as to their perceived improved access to and utilization of available health care services for their children. Surveys will be mailed to a sampling of parents/guardians of children enrolled in the CCC program who have received a minimum of 3 months of service.

Study #: **50020**
Principal Investigator: Jene Radcliffe-Shipman
Virginia Department of Health, Division of Women's and Infants' Health
Title of Protocol: "Sickle Trait Follow-up Services for Infants Born at VCU Medical Center"
Date approved: October 13, 2004
Description of Study: Children with sickle cell trait and hemoglobin C trait are identified through the Virginia Newborn Screening Program. The primary goal of this study is to develop and implement a pilot program to provide information to parents and offer them resources and follow up services. The pilot program will involve the mailing of information regarding the trait and referral sources. A survey will be used to evaluate the mailed materials and accessibility of referral sources.

Study #: **50021**
Principal Investigator: James Ellis
VCU Survey and Evaluation Research Laboratory
Title of Protocol: "Behavior Risk Factor Surveillance System (BRFSS) Additional Questions relating to Flu and Flu Vaccine Shortage"
Date approved: November 19, 2004
Description of Study: The purpose of this study is to add questions to the Behavioral Risk Factor Surveillance Survey regarding respondents' obtaining the flu vaccine during the 2004 – 2005 flu season in order to assess the response to the nationwide shortage of flu vaccine and its impact on the population.

Study #: **50022**
Principal Investigator: James Ellis
Title of Protocol: "Behavioral Risk Factor Surveillance System state-added Questions"
Date approved: December 26, 2004
Description of Study: The addition of 44 "state-added" questions to the CDC Behavioral Risk Factor Surveillance Survey master protocol. State-added questions pertain to diabetes, dental health, fire safety, suicidal ideation, women's health, epilepsy, cancer screening, tobacco use, and physical activity.

II. Any significant deviations from proposals as approved:

Study #: 40023
Principal Investigator: Angela H. Taylor
VCU Survey and Evaluation Research Laboratory
Title of Protocol: "TPPI: Norfolk Real Alternatives to Pregnancy Program"
Type of Review: Violation of Protocol
Description of Deviation P.I. received report from local evaluator regarding a history of data discrepancies and problems during the period 9/03 – 6/04. Repeated efforts to resolve those issues with program staff who were responsible for the data collection were attempted and also documented. Local evaluator describes instances of removal and possession of data by unauthorized individuals in violation of approved IRB protocol and multiple instances of apparent data tampering.
Description of Action: VDH IRB unanimously agreed to terminate approval of this study and requested that all activities related to this study be suspended and all data collected to date be destroyed.

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 2004		
Committee Members	**Qualifications for Service**	**Institutional Affiliation**
IRB CHAIR		
Kathy H. Wibberly	Ph.D. in Counseling Psychology & Senior Policy Analyst in Office of Health Policy and Planning	Virginia Department of Health
VOTING MEMBERS		
Lisa R. Ballance (temporarily inactive as of March 2004)	M.A. in English/Scientific Writing & Co-Director of the Office for Compliance Oversight, Office of Research	Virginia Commonwealth University
Rene S. Cabral-Daniels	J.D., M.P.H. & Director, Office of Health Policy and Planning	Virginia Department of Health
Bethany J. Geldmaker	Ph.D. in Nursing & Child Health Care Consultant	Virginia Department of Health
Gail J. Jennings	Ph.D. in Psychology & Program Director, Virginia Breast and Cervical Cancer Early Detection Program	Virginia Department of Health
H. Dennis Kade	Ph.D. in Clinical Psychology & Psychology Supervisor	Norfolk Department of Public Health and Tidewater Child Development Services
Gregory B. Stolcis	Ph.D. in Public Policy & Administration and Director, Acute Care Division, Center for Quality Health Care Services and Consumer Protection	Virginia Department of Health
Jessica L. Waugh	M.A. in Religious Studies (Ethics/Bioethics)	Independent Contractor, Editorial and Writing Services
ALTERNATE MEMBERS		
Thomas G. Franck (resigned March 2004)	M.D., M.P.H., Central Region Physician Consultant, Emergency Preparedness and Response Program	Virginia Department of Health
Gerges Siefen (resigned July 2004)	M.D., M.P.H., Epidemiologist/BRFSS Coordinator	Virginia Department of Health
Edward L. Van Oeveren (inactive member from March 2004 – December 2004 due to deployment)	J.D., M.D., M.P.H. & Director, West Piedmont Health District	West Piedmont Health District