REPORT TO THE COMMISSIONER:

ACTIVITIES OF THE VIRGINIA DEPARTMENT OF HEALTH INSTITUTIONAL REVIEW BOARD FOR CALENDAR YEAR 2005

REPORT TO THE COMMISSIONER:
ACTIVITIES OF THE VDH IRB FOR CALENDAR YEAR 2005

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 voluntarily registered, applied for, and received Federalwide Assurance for its IRB from OHRP in 2001. 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 VDH IRB Federalwide Assurance was granted a three year renewal by OHRP in 2004 (FWA00000274).

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 2005.

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

A. Full Board Reviews

Study #: 30005
Principal Investigator: Karen Day, DDS, MPH
Title of Protocol: "Fluoride Varnish Study"
Date approved: May 27, 2005
Description of Study: This study collects baseline and follow up data from Early Head Start and Head Start children regarding the effectiveness of the application of fluoride varnish to reduce dental decay.

B. Expedited Reviews:

Study #: 40048
Principal Investigator: Anneke Schroen, M.D., MPH
Title of Protocol: "The Impact of Mammography Access on Breast Cancer Tumor Size at Time of Diagnosis"
Date approved: January 3, 2005
Description of Study: This study uses Virginia Cancer Registry data to determine if there is a relationship between tumor size at diagnosis and patient distance to the nearest accredited mammography center.

Study #: 40049
Principal Investigator: John Ambrose, MPH, CHES
Title of Protocol: "Evaluation of Timely Communicable Disease Reporting by Local Providers in a Rural Virginia Health District"
Date approved: January 21, 2005
Description of Study: This study assesses whether communicable diseases that are required to be reported to the local health department are being reported in a timely and accurate manner at one health district.

Study #: 40050
Principal Investigator: Kathy Orchen, M.S., P.A., MPH
Title of Protocol: "Folic Acid Supplement Distribution Program"
Date approved: May 5, 2005
Description of Study: This study assesses the impact of folic acid distribution at family planning clinics on behaviors and pregnancy outcomes.

Study #: 40051
Principal Investigator: Jennifer Ann Morrow, Ph.D.
Title of Protocol: "Evaluation of the Talk2Me Toolkit"
Date approved: July 29, 2005
Description of Study: This study evaluates the effectiveness of the Talk2Me Toolkit in achieving its projected short and intermediate outcomes. The Talk2Me Toolkit was designed to help parents communicate more frequently and more effectively with their children regarding delayed sexual activity and abstinence.

Study #: 40052
Principal Investigator: William Blot, Ph.D.
Title of Protocol: "Southern Community Cohort Study (SCCS) Follow-Up Study for Cancer Incidence"
Date approved: June 6, 2005
Description of Study: This study uses Virginia Cancer Registry data to help identify the causes of increased risk of cancer and other diseases among residents of the South, with a particular focus on the disparity between rates for African-American versus other residents.

Study #: 40053
Principal Investigator: Dawn Wesson, Ph.D.
Title of Protocol: "West Nile Virus Infection and Outcomes of Pregnancy in Humans"
Date approved: August 3, 2005
Description of Study: This study gathers new information regarding the impact of West Nile Virus on pregnancy and pregnancy outcomes.

Study #: 40054
Principal Investigator: Allen Lewis, Ph.D.
Title of Protocol: "Evaluation of the Passport to Manhood Program"
Date approved: August 1, 2005
Description of Study: This study assesses the impact of the Passport to Manhood teen pregnancy prevention program in achieving its program goals.

Study #: 40055
Principal Investigator: Kathryn Laughon, Ph.D., RN
Title of Protocol: "Rural Women's Health Study"
Date approved: August 24, 2005
Description of Study: This study assesses the utility of a nurse delivered brief intervention on reducing STD/STI risk among women experiencing intimate partner violence.

Study #: 40056
Principal Investigator: Allen Lewis, Ph.D.
Title of Protocol: "Evaluation of the Postponing Sexual Involvement Program"
Date approved: August 31, 2005
Description of Study: This study assesses the impact of the Postponing Sexual Involvement teen pregnancy prevention program in achieving its program goals.

Study #: 40057
Principal Investigator: Kathryn Laughon, Ph.D., RN
Title of Protocol: "Risk Factors for Pregnancy Associated Intimate Partner Homicide"
Date approved: September 28, 2005
Description of Study: This study assesses the feasibility of conducting larger scale research to identify risk factors for pregnancy-associated intimate partner homicide. The study will try to describe the context of pregnancy-associated intimate partner homicides and determine if collecting needed documents and obtaining data from proxy informants is realistic.

Study #: 40059
Principal Investigator: John Bruce McClain, M.D.
Title of Protocol: "Collection of Blood Specimens for Tissue Sample Bank to Support Shipping Validation and Tuberculosis Assay Validation"
Date approved: November 9, 2005
Description of Study: This study assesses the plausibility of testing for TB using a blood sample. If this is plausible, it would result in a more reliable and efficient method than traditional skin testing.

Study #: 40060
Principal Investigator: Karen C. Day
Title of Protocol: "1999 Virginia Statewide Oral Health Needs Assessment"
Date approved: December 20, 2005
Description of Study: This study looks at the prevalence and severity of oral health outcomes among school age children in Virginia and assess whether there are disparities within the state and to determine risk factors which may contribute to these poorer outcomes.

C. Exemption Reviews

Study #: 50023
Principal Investigator: Linda Birtley
Title of Protocol: "Investigation of Barriers to Program Evaluation and Utilization of Evaluation Results"
Date approved: April 14, 2005
Description of Study: This study uses structured interviews with Virginia Abstinence Education Initiative Program staff to identify barriers to the program evaluation process and/or the utilization of the program evaluation results and make recommendations for quality improvement.

Study #: 50024
Principal Investigator: Karen Fauber, RD, MA
Title of Protocol: "Guidelines for Managing Asthma in Virginia Schools: A Team Approach Survey Project"
Date approved: June 1, 2005
Description of Study: This study assesses the effectiveness of the Asthma School Manual and corresponding educational sessions by surveying school staff and makes recommendations for process and quality improvements.

Study #: 50025
Principal Investigator: Diana C. Ocampo
Title of Protocol: "Long-term Consequences of West Nile Fever"
Primary Reviewer: Dennis Kade
Date approved: June 1, 2005
Description of Study: This study assesses lingering symptoms and functional outcomes of patients in Virginia who reported to the Virginia Department of Health with West Nile virus infection.

Study #: 50027
Principal Investigator: Alec Ulasevich.
Title of Protocol: "Evaluation of the Virginia Stop It Now! Media Campaign"
Date approved: July 26, 2005
Description of Study: This study assesses changes in knowledge, attitudes and behaviors related to child sexual assault as a result of the Stop It Now! campaign.

Study #: 50028
Principal Investigator: Jennifer Ann Morrow, Ph.D.
Title of Protocol: "Colonial Heights Focus Groups for the My Choice My Future Program"
Date approved: August 2, 2005
Description of Study: This focus group study assesses parental knowledge of existing teen pregnancy prevention programs in the community and solicits ideas about possible changes to those existing programs.

Study #: 50029
Principal Investigator: Theresa Taylor, RN, MPH
Title of Protocol: "Virginia Fetal and Infant Mortality Review (FIMR)"
Date approved: August 8, 2005
Description of Study: This study serves a public health surveillance function, using a multi-disciplinary team to review reports and data and conduct interviews in the event of fetal and infant deaths in order to determine the factors contributing to the death and to propose solutions.

Study #: 50030
Principal Investigator: Michelle White
Title of Protocol: "Intimate Partner Violence Survey of Medical Care Providers"
Date approved: August 30, 2005
Description of Study: This study examines how the issue of intimate partner violence is addressed by healthcare providers in Virginia. Results will be used to develop provider-specific trainings, curricula and educational materials for statewide use.

Study #: 50031
Principal Investigator: Linda Birtley
Title of Protocol: "Teen Pregnancy Prevention Initiative Program Evaluation: Investigation of Barriers to Program Evaluation and Utilization of Evaluation Results"
Date approved: November 10, 2005
Description of Study: This study uses structured interviews with Teen Pregnancy Prevention Initiative Program staff to identify barriers to the program evaluation process and/or the utilization of the program evaluation results and makes recommendations for quality improvement.

Study #: 50032
Principal Investigator: Susan Kennedy Spain
Title of Protocol: "Behavioral Risk Factor Surveillance System State-Added Questions 2006"
Date approved: November 21, 2005
Description of Study: This study entails the addition of state-added questions to the CDC Behavioral Risk Factor Surveillance System standard protocol. These questions include modules related to suicide, residential fire, sexual violence, intimate partner violence, anxiety and depression, fruits and vegetables, physical activity, smoking, asthma, oral health, hypertension, cholesterol, diabetes and folic acid.

II. Any significant deviations from proposals as approved:

Study #: 40039
Principal Investigator: Bridget J. McCarthy, Ph.D.
Title of Protocol: **"**Central Brain Tumor Registry of the United States (CBTRUS)"
Description of Deviation: During a mugging, a book bag containing a jump drive that contained a subset of data stored in SAS version XX format was stolen. The data subset included the following variables: month of birth; month of diagnosis; county number code.
Description of Action: The P.I. proposed corrective action steps to be taken to prevent future occurrences of this type of adverse event. These actions included password protecting all datasets and were seen as appropriate and adequate by the VDH IRB.

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 2005		
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 (resigned April 2005)	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		
Edward L. Van Oeveren	J.D., M.D., M.P.H. & Director, West Piedmont Health District	West Piedmont Health District
VACANT	N/A	N/A/

Virginia Department of Health
Institutional Review Board

MINUTES

January 10, 2005
10:30 AM – 12:30 PM

Members Present: Kathy Wibberly (Chair), Rene Cabral-Daniels, Bethany Geldmaker, Gail Jennings, Dennis Kade, Greg Stolcis, Jessica Waugh

Members Absent: Lisa Ballance, Ed Van Oeveren

Guests: None

General Items:

- **The meeting convened at 10:15 AM. A quorum was present.**
- **Minutes from the October meeting were unanimously approved with 1 abstention (Jessica Waugh).**
- Online tracking of protocols, reviews, and meetings a possibility in the future – let me know what you think!
    - http://www.irbsolution.com/

Meeting dates/schedule for 2005

- **Monday, April 4, 2005**
- **Monday, July 11, 2005**
- **Monday, October 3, 2005**

PRESENTATION OF NEW PROTOCOLS - EXEMPTION REVIEW:

Study #:	50020
Principal Investigator:	Jene Radcliffe-Shipman
Title of Protocol:	"Sickle Trait Follow-up Services for Infants Born at VCU Medical Center"
Primary Reviewer:	Dennis Kade
Discussion:	Reading level of the letter to parents was at an appropriate (7^{th} grade) reading level, but the informational brochures were at an approximately 8^{th} – 9^{th} grade reading level. Additionally, follow-up letter did not reference initial letter which may create confusion and/or anxiety for the parent. Recommendations were made regarding both these issues.
Description of Action:	Approved unanimously

Rene Cabral-Daniels joins meeting

Study #:	50021
Principal Investigator:	James Ellis
Title of Protocol:	"Behavior Risk Factor Surveillance System (BRFSS) Additional Questions relating to Flu and Flu Vaccine Shortage"
Primary Reviewer:	Gail Jennings
Discussion:	PI assumed that reader knew background about BRFSS methodology. This should not be assumed for future submissions.
Description of Action:	Approved unanimously with 1 abstention (Rene Cabral-Daniels)

Study #:	50022
Principal Investigator:	James Ellis
Title of Protocol:	"Behavioral Risk Factor Surveillance System state-added questions"
Primary Reviewer:	Rene Cabral Daniels
Discussion:	None
Description of Action:	Approved unanimously

PRESENTATION OF NEW PROTOCOLS - EXPEDITED REVIEW:

Study #:	40044
Principal Investigator:	Allen N. Lewis, Ph.D.
Title of Protocol:	"Reducing the Risk: City of Richmond Teen Pregnancy Prevention Initiative"
Primary Reviewer:	Greg Stolcis
Discussion:	Study was designed adequately, but protocol as initially submitted was very poorly done. PI was asked to edit and resubmit due to multiple grammatical, typographical and other errors. Although resubmitted version still had several grammatical errors, it was much improved.
Description of Action:	Approved unanimously

Study #:	40045
Principal Investigator:	Sarah Jane Brubaker, Ph.D.
Title of Protocol:	"Evaluation of the Postponing Sexual Involvement Program"
Primary Reviewer:	Rene Cabral-Daniels
Discussion:	PI had conflicting numbers of participants indicated in different locations of the protocol. Clarification as to exact numbers had to be obtained from the P.I.
Description of Action:	Approved unanimously

Rene Cabral-Daniels exits meeting

Study #: 40046
Principal Investigator: Allen N. Lewis, Ph.D.
Title of Protocol: "Passport to Manhood (PTM) Program Evaluation"
Primary Reviewer: Gail Jennings
Discussion: Proposal was well written. Recommendations were made to clarify compensation (there was mention of a drawing in the letter but not mentioned in the consent form) and to be more specific as to who would have access to the youth survey responses and how findings would be disseminated.
Description of Action: Approved unanimously

Jessica Waugh exits meeting

Study #: 40047
Principal Investigator: Tejpratap Tiwari, M.D.
Title of Protocol: "Risk Factors for Mortality Due to Pertussis among Infants in the U.S. – A Case Control Study"
Primary Reviewer: Greg Stolcis
Discussion: None
Description of Action: Approved unanimously

Study #: 40048
Principal Investigator: Anneke Schroen, M.D., MPH
Title of Protocol: "The Impact of Mammography Access on Breast Cancer Tumor Size at Time of Diagnosis"
Primary Reviewer: Bethany Geldmaker
Discussion: Unclear how significant the findings would be, but it is a minimal risk study. Hence, weighing potential risks against potential benefits did not pose a problem.
Description of Action: Approved unanimously

PRESENTATION OF INITIAL SUBMISSIONS - FULL BOARD REVIEW:

None

CONTINUATION REVIEWS/RENEWALS:

Study #: **30001**
Principal Investigator: Gale E. Grant, M.A., C.P.P.
Title of Protocol: "Evaluation of the Virginia Abstinence Education Initiative"
Discussion: None
Description of Action: Approved unanimously

Study #: **30003**
Principal Investigator: Karen Day, Director, Division of Dental Health
Title of Protocol: "Evaluation of a School Based Fluoride Rinse Program"
Discussion: None

Description of Action: Approved unanimously
Study #: 30004
Principal Investigator: Casey W. Riley, Director, Division of HIV/STD
Title of Protocol: "Behavioral Risk Assessment Survey of STD Clinic Attendees"
Discussion: None
Description of Action: Approved unanimously

Study #: 40002
Principal Investigator: Dr. Eugenia E. Calle
VDH Collaborator: Virginia Cancer Registry
Title of Protocol: "Follow-up of CPS-II Participants through Linkage with State Cancer Registries"
Discussion: None
Description of Action: Approved unanimously

Study #: 40003
Principal Investigator: Gary M. Marsh, Ph.D.
VDH Collaborator: Virginia Cancer Registry
Title of Protocol: "Cohort Mortality and Cancer Incidence Studies of the Stonewall, VA Facility"
Discussion: None
Description of Action: Approved unanimously

Study #: 40005
Principal Investigator: M. Norman Oliver, M.D., M.A.
VDH Collaborator: Virginia Cancer Registry
Title of Protocol: "Role of environment and diet in increased prostate cancer mortality in African Americans"
Discussion: None
Description of Action: Approved unanimously

Study #: 40012
Principal Investigator: Kathleen F. Gaffney, Ph.D., RN-CS, F/PNP
Title of Protocol: **"**Smoking Relapse Among Mothers of Infants"
Discussion: None
Description of Action: Approved unanimously

Study #: 40013
Principal Investigator: Allen Lewis
Title of Protocol: **"**PREG 10 Makin' Your Future Program Focus Groups for the Crater Teen Pregnancy Prevention Initiative"
Discussion: None
Description of Action: Study completed and closed.

Study #: 40015
Principal Investigator: Louise Wideroff, Ph.D., MSPH
Title of Protocol: "Family Health Study (Validation of a Family History of Cancer Questionnaire for Risk Factor Surveillance"
Discussion: None

Description of Action: Approved unanimously
Study #: 40024
Principal Investigator: Rachel K Jones, Ph.D.
Title of Protocol: **"**Parental Engagement Among Adolescents Using Clinical Reproductive Health Services"
Discussion: None
Description of Action: Approved unanimously

Study #: 40025
Principal Investigator: Allen Lewis
Title of Protocol: **"**TPPI: Crater – Evaluation of Making Your Future Program"
Discussion: None
Description of Action: Study completed and closed.

Study #: 40026
Principal Investigator: Allen Lewis
Title of Protocol: "TPPI: Crater – Evaluation of the Passport to Manhood Program
Discussion: None
Description of Action: Study completed and closed.

Study #: 40030
Principal Investigator: Ann Nichols-Casebolt, Ph.D.
Title of Protocol: "Factors Constraining Breastfeeding Choices Among Low Income Mothers"
Discussion: None
Description of Action: Approved unanimously

OTHER (MINOR MODIFICATIONS, ETC):

Study #: 50020
Principal Investigator: Jene Radcliffe-Shipman
Title of Protocol: "Sickle Trait Follow-up Services for Infants Born at VCU Medical Center"
Type of Review: **Minor Modification Request**
Change of letterhead from VCU to VDH.
Discussion: None
Description of Action: Approved unanimously.

Study #: 50022
Principal Investigator: James Ellis
Title of Protocol: "Behavioral Risk Factor Surveillance System state-added questions"
Type of Review: **Minor Modification Request**
Minor revisions to pre-notification letter.
Discussion: None
Description of Action: Approved unanimously.

Meeting was adjourned at 12:20 PM.

Virginia Department of Health
Institutional Review Board

MINUTES

April 4, 2005
11:00 AM – 1:00 PM

Members Present: Kathy Wibberly (Chair), Bethany Geldmaker, Dennis Kade, Greg Stolcis, Ed Van Oeveren,

Members Absent: Lisa Ballance, Rene Cabral-Daniels, Gail Jennings, Jessica Waugh

Guests: Karen Day, Elizabeth Lazar

General Items:

- The meeting convened at 11:00 AM. A quorum was present.
- Human Research Review Training by OHRP is being organized by VDRS and will be available via VDH videoconference system at a date/time to be determined.
- Updated SOP's are now available on the VDH website. C.V.s are now required of P.I.s
- Minutes from the January meeting were unanimously approved.

Meeting dates/schedule for 2005

- Monday, July 11, 2005
- Monday, October 3, 2005

PRESENTATION OF NEW PROTOCOLS - EXEMPTION REVIEW:

Study #:	50023
Principal Investigator:	Linda Birtley
Title of Protocol:	"Investigation of Barriers to Program Evaluation and Utilization of Evaluation Results"
Primary Reviewer:	Greg Stolcis and Rene Cabral-Daniels
Discussion:	Once again the quality of work being submitted by SERL was a topic of discussion. The submitted protocol assumed knowledge of the study and did not provide any of the needed background, writing had grammatical/typographical errors and was difficult to follow. Allen Lewis has been contacted regarding the need for better quality assurance prior to submission to VDH IRB.
Description of Action:	PI has been asked to revise and resubmit.

PRESENTATION OF NEW PROTOCOLS - EXPEDITED REVIEW:

Study #: 40049
Principal Investigator: John Ambrose, MPH, CHES
Title of Protocol: "Evaluation of Timely Communicable Disease Reporting by Local Providers in a Rural Virginia Health District"
Primary Reviewer: Bethany Geldmaker
Discussion: This "study" could probably have been conducted as part of standard epi surveillance quality assurance without having to undergo IRB review and this gray area was reflected in the intermixing of terminology used in the protocol. Many of these types of "studies" are being presented for IRB review due to the potential for publication or its potential for generating research at a later date.
Description of Action: Approved unanimously with the clarifications provided by the P.I.

PRESENTATION OF INITIAL SUBMISSIONS - FULL BOARD REVIEW:

Study #: 30005
Principal Investigator: Karen Day, DDS, MPH
Title of Protocol: "Fluoride Varnish Study"
Presenter: Karen Day, DDS, MPH and Elizabeth Lazar, MPH
Discussion: Discussion centered on the potential for the survey to be used for other WIC related purposes (e.g., collection of nutrition information), reading level of consent forms, the potential for allergic reactions and other side effects, potential confusion of ordering of race/ethnicity question.
Description of Action: Unanimous – Approvable with the following two conditions and one recommendation:

Conditions:

- Consent forms should be revised to a 6^{th} – 8^{th} grade reading level. This would be more consistent with the reading level found in the targeted population.
- Either the consent form and/or some other parent handout should provide the parent(s) with a contact person/number to call if they have concerns that their child may be experiencing a side effect or allergy to either the fluoride treatment of the latex. For example, the consent form could say something like: Although the chance of any side effects such as nausea, vomiting or an allergic reaction are very low, if you should have any concerns that your child might be experiencing some kind of side effect from the treatment, please contact…

Recommendation for PI's consideration:

- In the parent survey, one item collects data regarding Hispanic/Latino as an ethnicity that is prior to selection of race. Although this is standard questionnaire format now, experience has shown that this has the potential for causing confusion by the respondents. It is recommended that when respondents are filling out the questionnaire, someone be in the room and available to answer questions to minimize non-responses to the item set.

CONTINUATION REVIEWS/RENEWALS:

Study #: 40032
Principal Investigator: Fred Angulo
Title of Protocol: "Interview of Persons from which Enteric Bacterial Isolates Have Been Cultured with Uncommon Antimicrobial Resistance Patterns"
Discussion: None
Description of Action: Approved unanimously

Study #: 40033
Principal Investigator: Casey W. Riley
Title of Protocol: "Antiretroviral Drug Resistance Testing (ARDVDRT) in Individuals Newly Diagnosed with HIV"
Discussion: Drug Resistance Testing received a federal non-research determination in August 2004 and was designated by that determination as a part of routine HIV surveillance.
Description of Action: Study closed.

Study #: 40034
Principal Investigator: Casey W. Riley
Title of Protocol: "Estimating HIV Incidence by Using Population-based Serologic Method to Detect HIV-1 Infection"
Discussion: None
Description of Action: Approved unanimously

Study #: 40035
Principal Investigator: Beth Ehrensberger
Title of Protocol: "Listening to the Experts to Increase Cancer Screening in Virginia"
Discussion: Study has been completed and key findings were reviewed.
Description of Action: Study closed.

Study #: 40036
Principal Investigator: Tanya Bobo
Title of Protocol: "West Nile Virus Seroprevalence Study of Bird Handlers in Virginia"
Discussion: Study has been completed.
Description of Action: Study will be closed upon receipt of key findings.

OTHER (MINOR MODIFICATIONS, ETC):

Study #: 40012
Principal Investigator: Kathleen Gaffney
Title of Protocol: "Smoking Relapse Among Mothers if Infants"
Type of Review: **Minor Modification Request**
Discussion: Addition of site at Page County Health Department. No other changes to protocol.
Description of Action: Approved unanimously

Study #:	40032
Principal Investigator:	Fred Angulo
Title of Protocol:	"Interview of Persons from which Enteric Bacterial Isolates Have Been Cultured with Uncommon Antimicrobial Resistance Patterns"
Type of Review:	**Minor Modification Request**
Discussion:	Deleted name of contact person in consent form, but phone numbers and other contact information remain the same. Deleted a series of questions from the survey to make it shorter.
Description of Action:	Approved unanimously

Meeting was adjourned at 1:05 PM.

Virginia Department of Health
Institutional Review Board

MINUTES

July 11, 2005
10:30 AM – 12:30 PM

Members Present: Kathy Wibberly (Chair), Bethany Geldmaker, Gail Jennings, Dennis Kade, Greg Stolcis, Ed Van Oeveren, Jessica Waugh

Members Absent: Rene Cabral-Daniels

Guests: None

General Items:

- The meeting convened at 10:35 AM. A quorum was present.
- Paper entitled "Public Health Practice vs. Research" from the Council of State and Territorial Epidemiologists was disseminated and discussed.
- Minutes from the April meeting were unanimously approved.

Meeting dates/schedule for 2005

- Monday, October 3, 2005 (Bethany will not be able to attend)
- Meeting dates for 2006 will be set at the October meeting.

PRESENTATION OF NEW PROTOCOLS - EXEMPTION REVIEW:

Study #:	50023
Principal Investigator:	Linda Birtley
Title of Protocol:	"Investigation of Barriers to Program Evaluation and Utilization of Evaluation Results"
Primary Reviewer:	Greg Stolcis and Rene Cabral-Daniels
Discussion:	PI revised and resubmitted the protocol, which was greatly improved.

Description of Action: Approved unanimously.

Study #: 50024
Principal Investigator: Karen Fauber, RD, MA
Title of Protocol: "Guidelines for Managing Asthma in Virginia Schools: A Team Approach Survey Project"
Primary Reviewer: Rene Cabral-Daniels
Discussion: The PI stated that information from the study would be used to determine the effectiveness and make improvements to the Asthma School Manual, but the pre-post survey was implemented before and after an educational session. The reviewer was unclear as to the role and impact of the educational session on an assessment of the manual. The PI was asked for clarification. PI stated that the information requested from the participants
Description of Action: Approved unanimously.

Study #: 50025
Principal Investigator: Diana C. Ocampo
Title of Protocol: "Long-term Consequences of West Nile Fever"
Primary Reviewer: Dennis Kade
Discussion: Initial submission did not explicitly state that vulnerable populations would be excluded from the study. Reviewer also recommended providing clarification for the phrase "altered mental status". The PI responded back specifically stating that vulnerable populations would be excluded from the study and will be providing examples to better define "altered mental status."
Description of Action: Approved unanimously.

Study #: 50026
Principal Investigator: Jennifer Ann Morrow, Ph.D.
Title of Protocol: "Evaluation of the Talk2Me Toolkit"
Primary Reviewer: Ed VanOeveren
Discussion: Although the "subjects" being used for the focus groups were adults, the research requires participation of children and the purpose of the program is to change the behavior of children. Hence, children were still deemed the "subjects" of the research, disqualifying the study from exemption review. Additionally, responses are recorded in such a way (unique identifier for survey and first names used for transcript) that they could potentially be matched.
Description of Action: Disapproved (vote: 6 for disapproval, 1 abstention). PI will be asked to revise and resubmit for expedited review.

PRESENTATION OF NEW PROTOCOLS - EXPEDITED REVIEW:

Study #: 40050
Principal Investigator: Kathy Orchen, M.S., P.A., MPH
Title of Protocol: "Folic Acid Supplement Distribution Program"
Primary Reviewer: Jessica Waugh
Discussion: Study was low-risk with high potential benefit and included a request for a waiver of consent. P.I. did mistakenly indicate that informed consent

	would be obtained using a form. This mistake was corrected by the P.I. once it was noted.
Description of Action:	Approved unanimously.

Study #:	40052
Principal Investigator:	William Blot, Ph.D.
Title of Protocol:	"Southern Community Cohort Study (SCCS) Follow-Up Study for Cancer Incidence"
Primary Reviewer:	Gail Jennings
Discussion:	Protocol was well written, risks were low and precautions were taken to protect confidentiality.
Description of Action:	Approved unanimously.

Virginia Department of Health
Institutional Review Board

MINUTES

October 3, 2005
10:00 AM – 1:00 PM

Members Present: Kathy Wibberly (Chair), Rene Cabral-Daniels, Bethany Geldmaker, Gail Jennings, Dennis Kade, Ed Van Oeveren, Jessica Waugh

Members Absent: Greg Stolcis

Guests: None

General Items:

- The meeting convened at 10:18 AM. A quorum was present.
- Information about the Investigator 101 CD-ROM & User's Manual was shared.
    - We are awaiting a response regarding permission to make the entire training available on our https://va.train.org/ website.
    - In the meantime, our site license allows us to make copies and distribute the CD...if you would like a copy, please contact Kathy.
- Minutes from the July meeting were unanimously approved.

Meeting dates/schedule for 2006

- Wednesday, January 4
- Monday, April 3
- Monday, July 10
- Monday, October 2

For all dates, please keep the block of time between 10AM – 1PM open. Meetings will generally begin at 10:30AM and end by 12:30PM, but we need to allow for extra time in case we have a heavy load.

PRESENTATION OF NEW PROTOCOLS - EXEMPTION REVIEW:

Study #: 50027
Principal Investigator: Alec Ulasevich.
Title of Protocol: "Evaluation of the Virginia Stop It Now! Media Campaign"
Primary Reviewer: Rene Cabral-Daniels
Discussion: None.
Description of Action: Approved.

Study #: 50028
Principal Investigator: Jennifer Ann Morrow, Ph.D.
Title of Protocol: "Colonial Heights Focus Groups for the My Choice My Future Program"
Primary Reviewer: Greg Stolcis
Discussion: None.
Description of Action: Approved.

Study #: 50029
Principal Investigator: Theresa Taylor, RN, MPH
Title of Protocol: "Virginia Fetal and Infant Mortality Review (FIMR)"
Primary Reviewer: Gail Jennings
Discussion: Kathy will be presenting to the Regional Perinatal Councils regarding IRB requirements concerning research with the FIMR data later this month.
Description of Action: Approved.

Study #: 50030
Principal Investigator: Michelle White
Title of Protocol: "Intimate Partner Violence Survey of Medical Care Providers"
Primary Reviewer: Ed VanOeveren
Discussion: None.
Description of Action: Approved.

PRESENTATION OF NEW PROTOCOLS - EXPEDITED REVIEW:

Study #: 40051
Principal Investigator: Jennifer Ann Morrow, Ph.D.
Title of Protocol: "Evaluation of the Talk2Me Toolkit"
Primary Reviewer: Ed VanOeveren
Discussion: None.
Description of Action: Approved unanimously.

Study #: 40053
Principal Investigator: Dawn Wesson, Ph.D.
Title of Protocol: "West Nile Virus Infection and Outcomes of Pregnancy in Humans"
Primary Reviewer: Jessica Waugh
Discussion: None.

Description of Action: Approved unanimously.

Study #: 40054
Principal Investigator: Allen Lewis, Ph.D.
Title of Protocol: "Evaluation of the Passport to Manhood Program"
Primary Reviewer: Bethany Geldmaker
Discussion: None.
Description of Action: Approved unanimously.

Study #: 40055
Principal Investigator: Kathryn Laughon, Ph.D., RN
Title of Protocol: "Rural Women's Health Study"
Primary Reviewer: Greg Stolcis
Discussion: Some discussion was had regarding the NIH Certificate of Confidentiality. Rene volunteered to do some research regarding any case law that has come from it and Ed volunteered to do some research about it in general.
Description of Action: Approved unanimously.

Study #: 40056
Principal Investigator: Allen Lewis, Ph.D.
Title of Protocol: "Evaluation of the Postponing Sexual Involvement Program"
Primary Reviewer: Jessica Waugh
Discussion: None.
Description of Action: Approved unanimously.

Study #: 40057
Principal Investigator: Kathryn Laughon, Ph.D., RN
Title of Protocol: "Risk Factors for Pregnancy Associated Intimate Partner Homicide"
Primary Reviewer: Dennis Kade
Discussion: Although P.I. provided general content themes to be used for the interviews, there was no script provided.
Description of Action: Approvable pending receipt and review of the script for the structured interview.

PRESENTATION OF INITIAL SUBMISSIONS - FULL BOARD REVIEW:

None

CONTINUATION REVIEWS/RENEWALS:

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

Study #: 40016
Principal Investigator: Melvin Wilson
Title of Protocol: **"**Early Family Centered Prevention of Conduct Disorder and Drug use Risk in Rural Populations"

Discussion: None.
Description of Action: Approved unanimously.

Study #: 40019
Principal Investigator: Allen Lewis, Ph.D.
Title of Protocol: **"**TPPI: Portsmouth – Becoming a Responsible Teen (BART) Project Outcome Evaluation Study"
Discussion: None.
Description of Action: Approved unanimously.

Study #: 40020
Principal Investigator: Allen Lewis, Ph.D.
Title of Protocol: **"**TPPI: Richmond – Evaluation of Teen Outreach Program (TOP)"
Discussion: None.
Description of Action: Study closed.

Study #: 40021
Principal Investigator: Allen Lewis, Ph.D.
Title of Protocol: **"**TPPI: Eastern Shore Teen Pregnancy Prevention Program"
Discussion: None.
Description of Action: Approved unanimously.

Study #: 40022
Principal Investigator: Allen Lewis, Ph.D.
Title of Protocol: **"**TPPI: Alexandria – Evaluation of Pro-Teen/Pro-Youth and Project Step Out Program"
Discussion: None.
Description of Action: Approved unanimously.

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

Study #: 40028
Principal Investigator: Allen Lewis, Ph.D.
Title of Protocol: **"**TPPI: Evaluation of the Postponing Sexual Involvement Program at Three Sites in Virginia"
Discussion: There appear to be a series of these studies that provide little yield of information. There is a requirement to evaluate these programs, but they are structured in such a way (recruitment and retention issues) where a pre-post survey does not yield valid results.
Description of Action: Study closed.

Study #: 40030
Principal Investigator: Ann Nichols-Casebolt, Ph.D.
Title of Protocol: **"**Factors Constraining Breastfeeding Choices Among Low Income Mothers"

Discussion: There was interest in finding out from the P.I. how many of the participants were part of WIC (response: 62 WIC participants were eligible to participate and 40 completed the questionnaires).
Description of Action: Study closed.

Study #: 40037
Principal Investigator: Gary M. Marsh, Ph.D.
Title of Protocol: "The Cohort Mortality and Cancer Incidence Studies of the Rahway, NJ Facility"
Discussion: None.
Description of Action: Approved unanimously

Study #: 40038
Principal Investigator: H. Paul Brumund
Title of Protocol: "US SARS-CoV Cases: One Year Follow-up Study"
Discussion: None.
Description of Action: Study closed.

Study #: 40039
Principal Investigator: Bridget J. McCarthy, Ph.D.
Title of Protocol: "Central Brain Tumor Registry of the United States (CBTRUS)"
Discussion: None.
Description of Action: Approved unanimously

Study #: 40040
Principal Investigator: Meir J. Stampfer, M.D., Dr. PH
Title of Protocol: "Cohort Cancer Registry Follow-up Study"
Discussion: None.
Description of Action: Approved unanimously

Study #: 40041
Principal Investigator: Elizabeth Eustis Turf, Ph.D.
Title of Protocol: "The Epidemiology of Human Rabies Postexposure Prophylaxis in Virginia"
Discussion: None.
Description of Action: Study closed.

(Jessica Waugh left the meeting at this point)

Study #: 40042
Principal Investigator: Angela H. Taylor, MPA
Title of Protocol: "An Assessment of Outcome Evaluation for the Virginia Department of Health's Adolescent Sexual Health Initiatives"
Discussion: None.
Description of Action: Study closed.

Study #: 40044
Principal Investigator: Allen Lewis, Ph.D.
Title of Protocol: "TPPI: Richmond – Evaluation of the Reducing the Risk Richmond Pregnancy Program"
Discussion: None.

Description of Action: Approved unanimously

Study #: 40045
Principal Investigator: Sarah Jane Brubaker, Ph.D.
Title of Protocol: **"**TPPI: Crater – Evaluation of the Postponing Sexual Involvement Program"
Discussion: None.
Description of Action: Study closed.

Study #: 40046
Principal Investigator: Sarah Jane Brubaker, Ph.D.
Title of Protocol: **"**TPPI: Crater – Evaluation of the Passport to Manhood Program"
Discussion: None.
Description of Action: Study closed.

OTHER (MINOR MODIFICATIONS, ETC):

Study #: 40019
Principal Investigator: Allen Lewis, Ph.D.
Title of Protocol: **"**TPPI: Portsmouth – Becoming a Responsible Teen (BART) Project Outcome Evaluation Study"
Type of Review: **Minor Modification Request**
Description: Addition of two more cohorts to increase sample size.
Discussion: None.
Description of Action: Approved unanimously

Study #: 40021
Principal Investigator: Allen Lewis, Ph.D.
Title of Protocol: TPPI: Eastern Shore Teen Pregnancy Prevention Program"
Type of Review: **Minor Modification Request**
Description: Addition of two more cohorts to increase sample size.
Discussion: None.
Description of Action: Approved unanimously

Study #: 40022
Principal Investigator: Allen Lewis, Ph.D.
Title of Protocol: **"**TPPI: Alexandria – Evaluation of Pro-Teen/Pro-Youth and Project Step Out Programs"
Type of Review: **Minor Modification Request**
Description: Spanish translation of survey to be added due to large numbers of Hispanic students enrolled in the program and addition of two more cohorts to increase sample size.
Discussion: None.
Description of Action: Approved unanimously

Study #: 40039
Principal Investigator: Bridget J. McCarthy, Ph.D.
Title of Protocol: **"**Central Brain Tumor Registry of the United States (CBTRUS)"
Type of Review: **Adverse Event**
Description: During a mugging, a book bag containing a jump drive that contained a subset of data stored in SAS version XX format was stolen. The data subset included the following variables: month of birth; month of

	diagnosis; county number code). Action steps to prevent future issues being taken by the P.I. will include password protecting all datasets.
Discussion:	More information is needed regarding the level of password protection and/or encryption of data, the processes for transport of data, and why data needs to be moved on portable devices instead of access through the network.
Description of Action:	Tabled pending further information (further information was received from the P.I. and reviewed. Corrective action proposed and steps taken to prevent future occurrences of this type adverse event are seen as appropriate and adequate and have been approved.

Study #:	40044
Principal Investigator:	Allen Lewis, Ph.D.
Title of Protocol:	**"**TPPI: Richmond – Evaluation of the Reducing the Risk Richmond Pregnancy Program"
Type of Review:	**Minor Modification Request**
Description:	Addition of two more cohorts to increase sample size
Discussion:	None.
Description of Action:	Approved unanimously

Study #:	40051
Principal Investigator:	Jennifer Ann Morrow, Ph.D.
Title of Protocol:	"Evaluation of the Talk2Me Toolkit"
Type of Review:	**Minor Modification Request**
Description:	Extension of project period to December 2005 due to delays in data collection and inclusion of incentive payment of $65 per participant (revised protocol and consent form with this change has been submitted)
Discussion:	None.
Description of Action:	Approved unanimously

Study #:	50012
Principal Investigator:	Allen Lewis, Ph.D.
Title of Protocol:	**"**TPPI: Roanoke: Evaluation of the Teen Outreach Program, For Males Only Program, and Roanoke Adolescent Health Program"
Type of Review:	**Minor Modification Request**
Description:	Minor revisions to surveys (addition of several items and minor wording changes).
Discussion:	None.
Description of Action:	Approved unanimously

Meeting was adjourned at 12:50 PM.