



COMMONWEALTH OF VIRGINIA
DEPARTMENT OF SOCIAL SERVICES
Office of the Commissioner

Anthony Conyers, Jr.
COMMISSIONER

October 1, 2007

MEMORANDUM

TO: The Honorable Timothy B. Kaine
Governor of Virginia

General Assembly of Virginia

FROM: Anthony Conyers, Jr.

A handwritten signature in black ink that reads "Anthony Conyers, Jr." with a stylized flourish at the end.

SUBJECT: Annual Report on Human Research

Section 63.2-218 of the *Code of Virginia* requires the State Board of Social Services to adopt regulations regarding human research. The statute further requires that the regulations provide for an annual report to the Governor and General Assembly on the human research projects reviewed and approved.

In May 2005, the Department of Social Services established the Institutional Review Board to serve as its human research committee. The Institutional Review Board is charged with reviewing, approving and monitoring research conducted by the Department of Social Services, local departments of social services, contractors and licensed facilities. The enclosed report addresses the Department of Social Services' human research activities for state fiscal year 2007.

AC:lrn
Enclosure

VIRGINIA DEPARTMENT OF SOCIAL SERVICES
INSTITUTIONAL REVIEW BOARD

ANNUAL REPORT, STATE FISCAL YEAR 2007:
HUMAN RESEARCH PROJECTS

Prepared by:

Office of Research
Division of Strategy Management and Research

August 2007

**Annual Report: Virginia Department of Social Services
Institutional Review Board, State Fiscal Year 2007**

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Annual Report: Virginia Department of Social Services Institutional Review Board, State Fiscal Year 2007

Executive Summary

The purpose of this report is to provide the General Assembly with a summary of the activities of the Virginia Department of Social Services' human research committee -- also referred to as the Institutional Review Board (IRB) -- for State Fiscal Year 2007 (July 1, 2006 – June 30, 2007). Section 63.2-218 of the *Code of Virginia* requires the Virginia Department of Social Services (VDSS) to establish regulations regarding human subjects research and to form a human research committee or Institutional Review Board. The IRB is charged with reviewing, approving, and monitoring research conducted or authorized by the Department, local departments of social services, contractors, and VDSS-licensed facilities.

The VDSS Human Subject Research regulations were published in the *Virginia Register of Regulations* on August 12, 1993. In August 2003 and, again, in August 2007, VDSS published these regulations (i.e., 22 VAC 40-890 et seq.) in the *Virginia Register of Regulations*, to provide the opportunity for periodic public review and comment. The latter review period extends through September 10, 2007. In May 2005, VDSS reconstituted its human research committee by creating an Institutional Review Board, and in January 2006, it registered as a domestic IRB with the U.S. Department of Health and Human Services, Office for Human Research Protections (IRB # 00005238, Virginia Department of Social Services IRB #1). In December 2006, the Office for Human Research Protections approved the VDSS IRB for Federalwide Assurance (as FWA00010976).

Research involving VDSS clients generally involves no risk of physical harm, because it is not clinical research but rather observational studies of human behavior. The potential risks for VDSS studies most often involve issues of clients' privacy and, to a lesser extent, psychological harm (for example, from surveys that include sensitive questions). The VDSS IRB has a responsibility to protect clients' privacy and, more generally, to minimize the risks of research activities to VDSS clients.

In State Fiscal Year 2007, the VDSS IRB reviewed eight (8) proposed research studies. Three studies qualified for exemption review, two qualified for expedited review, and three were continuation reviews of previously approved, exempted research.

**Annual Report: Virginia Department of Social Services
Institutional Review Board, State Fiscal Year 2007**

Study Mandate

The purpose of this report is to provide the General Assembly with a summary of the activities of the Virginia Department of Social Services' Institutional Review Board (IRB) for State Fiscal Year 2007. The IRB, or human research committee, is charged with reviewing, approving, and monitoring research conducted or authorized by the Department, local departments of social services, contractors, and VDSS-licensed facilities.

Legal authority for the IRB is provided by § 63.2-218 of the *Code of Virginia*, which requires the Virginia Department of Social Services (VDSS) to establish regulations regarding human subjects research and to form a human research committee, also referred to as the Institutional Review Board (IRB). The VDSS' Human Subject Research regulation was published in the *Virginia Register of Regulations* on August 12, 1993. In May 2005, VDSS reconstituted its human research committee by creating an Institutional Review Board. In January 2006, VDSS registered the Institutional Review Board as a domestic IRB with the U.S. Department of Health and Human Services, Office for Human Research Protections. In December 2006, the Office for Human Research Protections approved the VDSS IRB for Federalwide Assurance (as FWA00010976).

Section 63.2-218 of the *Code of Virginia* requires the IRB “to submit to the Governor, the General Assembly, and the Commissioner at least annually a report on the human research projects reviewed and approved by the committee and shall require the committee to report any significant deviations from the proposals as approved.” This report fulfills that mandate.

Introduction

A key foundation for establishing human subjects research regulations is the National Research Act of 1974 (Public Law 93-348), which created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. In April 1979, the Commission produced a landmark document, known as The Belmont Report¹ (<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>), to provide guidance for protecting human subjects involved in research. Public attention on the welfare of individuals participating in research climaxed during the Nuremberg Trials after World War II, resulting in the creation of the Nuremberg Code and other rules that provide limited direction for physicians and scientists conducting research using human subjects. Based on the three guiding principles outlined in the Belmont Report (i.e., respect of persons, beneficence, and justice), current federal and state regulations provide systematic processes for protecting the rights and welfare of individuals who participate in research activities.

¹ The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. Washington, D.C.: U.S. Printing Office, 1979.

The Office for Human Research Protections (OHRP), an office of the U.S. Department of Health and Human Services (HHS), is responsible for ensuring the rights and welfare of individuals who participate in research activities supported by or conducted by HHS. OHRP oversees compliance with federal regulations on human subjects research established in 45 CFR Part 46 (1985).

In 1992, the Virginia General Assembly required the VDSS to establish a human subject research committee and promulgate state regulations concerning the review and approval of research conducted by VDSS, local departments of social services, and VDSS-licensed facilities and contractors (§§ 63.2-217 and 63.2-218). In August of 1993, VDSS published human research regulations in the *Virginia Register of Regulations*. In August 2003 and August 2007, VDSS published these regulations (22 VAC 40-890) in the *Virginia Register of Regulations* to provide the opportunity for periodic public review and comment. The latter review period extends through September 10, 2007.

In May 2005, VDSS reconstituted its human research committee by creating an Institutional Review Board, made up of seven members appointed by the Commissioner of VDSS. (Appendix B lists the current members of the IRB.) In January 2006, VDSS registered the Institutional Review Board as a domestic IRB with the U.S. Department of Health and Human Services, Office for Human Research Protections (IRB #00005238, VDSS IRB #1). In December 2006, the Office for Human Research Protections approved the VDSS IRB for Federalwide Assurance (as FWA00010976).

Current review standards employed by the VDSS IRB are based on the guiding principles of the Belmont Report -- respect of persons, beneficence, and justice -- and incorporate the requirements of informed consent, risk/benefit assessment, protection of privacy, and equitable selection of research subjects, and comply with the federal regulations on human subjects research established in 45 CFR Part 46 (1985).

Research involving VDSS clients is not biomedical in nature. Typically, VDSS clients participate in social or behavioral studies and in evaluations. Unlike medical studies, physical risk from this type of research is very rare. Most often, potential risks in VDSS-related studies involve issues of privacy. Research projects may also include survey questions on subjects that are psychologically or sociologically sensitive. The VDSS IRB reviews such research in advance to ensure that the rights of our clients are protected and that the proposed research maintains the privacy and welfare of the participants.

Human Research Activities for State Fiscal Year 2007

Staff in the VDSS Office of Research is responsible for administering the IRB and ensuring VDSS compliance with federal and state regulations on human subjects research. The VDSS Director of Research serves as the chair of the IRB and a research associate coordinates the administration of the IRB and proposal reviews. Major activities in support of the IRB for SFY 2007 included:

- Reviewing federal and state regulations on human subjects research and guidelines from various sources on IRB administration, policies and procedures;
- Reviewing and incorporating into the third edition of the *VDSS IRB Policies and Procedures Manual* (July 2006) (see <http://www.dss.virginia.gov/about/irb.cgi>, “Policies and Procedures/Manual”), the most recent revisions to federal OHRP regulations which were effective June 23, 2005.
- Attending a one-day workshop on the operation and regulatory basis for operating IRBs, presented by staff of the Office for Human Research Protections (OHRP), U.S. Department of Health and Human Services.

Human Research Projects Reviewed

VDSS’ IRB conducted an expedited review of two research proposals during State Fiscal Year 2007, exempted three research proposals from further review, and approved continuation reviews of three previously approved studies. The following section summarizes each proposal received and the decisions reached by the IRB.

Study #: 2007-01R
Principal Investigator: Karen A. Roberto
Center for Gerontology
Virginia Polytechnic Institute and State University
Title of Protocol: “Public Guardians/Conservators in Virginia: A Statewide Needs Assessment”
Date Approved: October 4, 2006
Description of Study: In response to a request by the Virginia Department for the Aging (VDA), the Center for Gerontology at Virginia Polytechnic Institute and State University will conduct a statewide needs assessment to estimate the: (1) Current unmet need for Public Guardian/Conservators in Virginia, and (2) Projected unmet need for Public Guardian/Conservators in Virginia for Fiscal Years 2010, 2015, and 2025. An analysis of the administrative data gathered will provide projections for the need for Public Guardianship that will assist the Commonwealth, both VDA and state legislators, in their short-and long-term planning for expanding this program.

The IRB approved this state-sponsored needs assessment as exempt from further review, because it develops the projected assessments using aggregate administrative data for the current and future fiscal years.

Study #: 2007-02Y
Principal Investigator: Matthew R. Young, Master’s Graduate Student
The College of William and Mary
Title of Protocol: “Policy and Budget Analysis of Virginia’s TANF Program, September 2006”
Date Approved: October 30, 2006
Description of Study: As part of the Master’s degree course work, this research proposes to analyze the statistical relationship between selected TANF data elements – application, case, and client – from September 2006. The proposal was first approved by

the Director of the Division of Benefit Programs before being forwarded, for review, by the IRB.

Given the nature of the data request and prior approval by the Division of Benefit Programs for access to the data, the IRB chose to forego an exempt review, opting instead to have the researcher sign and return the IRB Assurance of Confidentiality and Data Use form. This form identifies the data request for IRB records and ensures that the researcher agrees to adhere to the confidentiality and privacy provisions addressed in it.

Study #: 2007-03J
Principal Investigator: Shelly L. Jackson, Ph.D.
Institute of Law, Psychiatry and Public Policy
University of Virginia
Title of Protocol: “Financial Abuse of the Elderly vs. Other Forms of Elder Abuse: Assessing Their Dynamics, Risk Factors and Society’s Response”
Date Approved: March 1, 2007
Description of Study: This study will systematically obtain reliable empirical information regarding (1) factors that contribute to or are associated with the financial abuse of the elderly as opposed to other forms of elder abuse, (2) what triggers and promotes the reporting of this abuse, (3) what facilitates and limits investigations of this abuse, (4) what steps are taken in response to reports of this abuse and the effectiveness of these steps, and (5) how society’s efforts to prevent and ameliorate this abuse can be enhanced. A major goal is to understand when, by whom, and under what circumstances financial abuse of the elderly—and other forms of elder abuse—is reported to adult protective services. Since it is generally believed that elder abuse is underreported, this research is designed to learn more about the disclosure process in an effort to address this underreporting. Finally, the research is interested in learning more about the APS response once abuse comes to the attention of APS -- in the actual response of APS but also in the perceptions of the elders regarding this response (e.g., whether they felt the APS investigation and response was timely and effective).

The IRB approved this research on an expedited basis.

Study #: 2007-04Z
Principal Investigator: Dennis Zeller, Ph.D.
Hornby Zeller Associates, Inc. (HZA)
Troy, NY
Title of Protocol: “Workload Measures for Virginia Local Departments of Social Services: An Update”
Date Approved: March 20, 2007
Description of Study: This study will update the HZA 2000 “Workload Measures” study for local Departments of Social Services. It requires examining two pieces of information: (1) the time that local workers (i.e., case workers, program supervisors, and case support workers) have available for case-specific work, and (2) the time required to handle cases appropriately, that is, according to policy and procedure.

As an agency-sponsored study (co-sponsored by the League of Social Services Directors), designed to evaluate the staffing needs of local programs involving benefits, family services, employment services, and child care, the IRB approved this administrative study as exempt from further review.

Study #: 2007-05H
Principal Investigator: Kevin Hollenbeck, Senior Economist
W.E. Upjohn Institute for Employment Research
Title of Protocol: “Consulting on/Evaluation of State Workforce Programs”
Date Approved: March 27, 2007
Description of Study: Under contract to the Governor’s workforce office, the researcher proposes to use administrative data about TANF/VIEW and FSET participants, then match and merge these participants with VEC quarterly wage data in order to compute various performance measures. Specific measures include employment and earnings for the 2nd and 4th full quarters after exiting the respective programs as well as any credential earning that occurs within 12 months of exiting the given program.

The IRB approved this research on an expedited basis

Continuation Reviews In addition to the above five IRB reviews, the IRB has on file three annual Continuation Reviews, two for two Child Care studies, previously determined as not requiring IRB review: (1) “Curriculum Development,” Fairfax County Office for Children, Gail Bjorklund, Director and Principal Investigator, filed December 16, 2005; and (2) “Investing in Virginia’s Children Evaluation,” Dr. Margaret Camarena, Principal Investigator, Old Dominion University, filed June 22, 2006. The third annual Continuation Review is for the “4th National Incidence Study of Child Abuse and Neglect (NIS-4),” Dr. Andrea Sedlak, Project Director and Principal Investigator, filed September 21, 2006.

Significant Changes to Approved Proposals

During State Fiscal Year 2007, the IRB received no requests for significant changes to previously approved research protocols.

IRB Membership

The State Board of Social Services human research regulation requires that IRB members “ensure the competent, complete, and professional review of human research.” The Commissioner of VDSS appointed seven members to the IRB in May 2005. Five of the appointed members represent various divisions and expertise of the Department, and bring a wealth of knowledge and experience related to VDSS programs and constituents. Additionally, regulation requires that two members hold no affiliation with the VDSS. Two members are members of the community at large, including one member of the clergy. The current IRB members fully meet the membership requirements of both state and federal human research regulations. Appendix B identifies the name, area of expertise and education, and affiliation with the Department for each current IRB member.

IRB Meetings

The VDSS IRB did not hold a meeting of the full board during the fiscal year. Subsets of IRB members met to discuss individual studies.

Results of Approved Research

The VDSS IRB has requested that each of the investigators responsible for the research projects approved in State Fiscal Year 2007 submit a copy of their final research reports at the conclusion of their research activities. On April 10, 2007, the IRB received an electronic copy of the dissertation of Dr. Susan J. Murdock, *Conceptualizing Hoarding Behavior Among Elderly Women: A Mixed-Methods Approach*, November 2006.

APPENDIX A

STUDY MANDATE

1. *Code of Virginia*

§ 63.2-218. Board to adopt regulations regarding human research.

The Board shall adopt regulations to effectuate the provisions of Chapter 5.1 (§ 32.1-162.16 et seq.) of Title 32.1 for human research, as defined in § 32.1-162.16, to be conducted or authorized by the Department, any agency or facility licensed by the Department, or any local department. The regulations shall require the human research committee to submit to the Governor, the General Assembly, and the Commissioner at least annually a report on the human research projects reviewed and approved by the committee and shall require the committee to report any significant deviations from the proposals as approved.

(1992, c. 603, § 63.1-25.01; 2002, c. 747.)

APPENDIX B

VDSS IRB MEMBERSHIP, 2005-2007

VDSS Institutional Review Board		
Name	Qualification for Service	Institutional Affiliation
Erik Beecroft, Chair	Ph.D., Economics Director of Research	Virginia Department of Social Services, Division of Strategy Management & Research
Mary Disse	B.A., Psychology Post-Baccalaureate Certificate in Information Systems	Virginia Department of Social Services, Division of Benefit Programs
Kathy Hoke	Ph.D., Mathematics Associate Dean for Research Support Director, Graduate School of Arts and Sciences	University of Richmond
Cynthia Holdren	Master's in Public Administration Manager, Management Services Unit	Virginia Department of Social Services, Division of Child Support Enforcement
Lynette Isbell	B.S., Psychology Assistant Director	Virginia Department of Social Services, Division of Family Services
Robert Pyndell	B.A., Business Administration Financial Analyst	Virginia Department of Social Services, Division of Child Care and Development
James Nesmith	M. Div. Urban Minister	West Broad Church of Christ Richmond, Virginia