

A Report of the
Department of Social Services
Commonwealth of Virginia

**ANNUAL REPORT ON HUMAN
RESEARCH
State Fiscal Year 09**

to the Governor and the
General Assembly of Virginia

October 2009



COMMONWEALTH OF VIRGINIA
DEPARTMENT OF SOCIAL SERVICES
Office of the Commissioner

Anthony Conyers, Jr.
COMMISSIONER

August 4, 2009

MEMORANDUM

TO: The Honorable Timothy M. Kaine
Governor of Virginia

Members, General Assembly

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

I am pleased to submit the Department of Social Services' Annual Report on Human Research for State Fiscal Year 09, prepared pursuant to the § 63.2-218 of the Code of Virginia. If you have questions or need additional information concerning this report, please contact me.

AC/twa

Preface

Section 63.2-218 of the Code of Virginia (Code) requires the State Board of Social Services to adopt regulations regarding human research. The statute further requires the human research committee, referred to as the Institutional Review Board (IRB), to provide an annual report to the Governor and General Assembly on the human research projects reviewed and approved during the operating year:

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.

This report on human research projects reviewed and approved by the IRB during State Fiscal Year (SFY) 09 is in response to the mandate in § 63.2-218.

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Executive Summary

In SFY 09, the Department of Social Services' (DSS) human research committee, referred to as the IRB, reviewed three proposed research studies. One study qualified for exemption review, and two qualified for expedited review. In addition, one study modified its research protocol to increase participation, and two ongoing studies were completed.

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

Annual Report: DSS IRB, SFY 09

Report Mandate

The purpose of this report is to provide the Governor and the General Assembly with a summary of the activities of the DSS' IRB for SFY 09 (July 1, 2008 through June 30, 2009). The IRB is charged with reviewing, approving, and monitoring research conducted or authorized by DSS, local departments of social services, DSS contractors, and DSS licensed facilities.

Section 63.2-218 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.”

Introduction

Research involving DSS clients is not biomedical in nature. Typically, DSS 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, the potential risk in DSS-related studies involves privacy issues. DSS-related research projects may also include survey questions concerning subjects that are psychologically or sociologically sensitive.

The IRB reviews such research in advance to ensure that the rights of clients are protected and that the proposed research maintains the privacy and welfare of the participants.

Human Research Activities for SFY 09

The DSS Office of Research is responsible for administering the IRB and ensuring compliance with federal and state regulations regarding human subject research. The DSS Director of Research serves as chair of the IRB and a senior research associate coordinates administration of the IRB and proposal reviews. Appendix B contains a list of IRB members.

Major activities in support of the IRB for SFY 09 included:

- Reviewing ideas for studies and the relevant IRB regulations and requirements with the principals;
- Reviewing research protocols submitted for review and determining whether, and when, they meet the criteria for IRB approval; and
- Requesting that annual Continuation Review forms be completed by principal investigators for studies underway for more than a year.

Projects Reviewed

Study #: 2009-01/P
Principal Investigator: Kathy Park
Assistant Director
Children’s Research Center, Madison, WI
Title of Protocol: “High-Risk TANF Families” Project with Norfolk DSS
Date Approved: October 14, 2008
Description of Study: This multiyear, federally funded study is being conducted in several sites, one being the Norfolk DSS, to improve the safety and well-being of children by identifying TANF-eligible families with a high probability of future maltreatment and by engaging these families in prevention services. Phase I includes designing and implementing a child maltreatment program for such families, while Phase II builds on Phase I by refining the case-management system, strengthening program implementation, and evaluating the program’s impact on child maltreatment rates using a randomized experimental design.

The IRB approved the study, in process, on an expedited basis, and all four staff members with access to Norfolk DSS client data signed the Assurance of Confidentiality form. The IRB also requested the CRC to revise the Informed Consent form being used, as suggested, to conform to federal requirements. The CRC revised the Consent form accordingly and immediately implemented its use in Norfolk.

Study #: 2009-02/Os
Principal Investigator: Sheri Osborne
Director of Training
Child Development Resources, Norge, VA
Title of Protocol: “1-2-3 READ! Virginia” Evaluation Plan
Date Approved: November 3, 2008
Description of Study: This study will continue the evaluation of child care training programs, similar to an evaluation performed under a previous DSS contract. The Evaluation Plan includes questions designed to determine the productivity of teacher coaching and training on the 1-2-3 READ! curriculum; teachers’ reactions to the training and to on-site coaching, where provided; teachers’ levels of learning; and their use of the knowledge and skills gained from this training in their home environment.

The IRB considered this project exempt from further review, both as an evaluation study and because the teachers trained cannot be identified from the evaluation. It required the Principal Investigator to sign an Assurance of Confidentiality form.

Study #: 2009-03/B
Principal Investigators: Isabel Bradburn, Ph.D., and Aaron Schroeder, Ph.D.
Child Development Center for Learning & Research and
Institute for Policy and Governance (respectively)
Virginia Tech, Blacksburg, VA
Title of Protocol: “Building an Integrated Child and Family Policy Research
Data Capacity for the Commonwealth of Virginia”
Date Approved: May 14, 2009
Description of Study: This federally funded, three-year study – awarded to the
Office of Early Childhood Development (OECD), DSS – is a partnership with several
agencies (e.g., Department of Education, Health Department), and with Virginia Tech,
which serves as the primary consultant. The purpose of the project is to develop an
integrated, interagency data system that enables state and local policymakers to assess the
impacts of initiatives by the OECD, state Department of Education, state Health
Department and other agencies (i.e., public, non-profit, and private) on: (1) the quality of
child care available for and used by low-income working parents and by at-risk families
in support of child well-being and desired parental outcomes; and (2) other policy issues
that affect child care, the quality of early education, and family and child outcomes.

The IRB approved this study on an expedited basis after receiving signed agreements from the Principal Investigators and research team to meet specified data confidentiality and safety conditions, including Assurances of Confidentiality and a plan to destroy identifying DSS client information as soon as the study is finished with the client-linking information.

Continuation Reviews and Modifications

One ongoing project completed an annual Continuation Review form during the fiscal year, in conjunction with making minor modifications to its research design to increase the recruitment, participation, and sample size of elderly clients. The modification consisted of using non-client-identifying information from the state Adult Services automated system to alert case workers in local departments to the existence of prospective clients, by case number, for the study:

(1) “Financial Abuse of the Elderly vs. Other Forms of Elder Abuse: Assessing Their Dynamics, Risk Factors and Society’s Response,” Shelly L. Jackson, Ph.D., Principal Investigator, filed August 8, 2008 and March 17, 2009, covering research activities through August 9, 2010.

Significant Changes to Approved Projects

Other than the minor modifications covered in the project and paragraph above, there were none.

IRB Meetings

The IRB did not hold a meeting of the full board during the fiscal year. Subsets of IRB members, however, did meet several times during the year to discuss individual studies requiring review, modification, or the application of federal and state regulations to specific data-related issues.

Results of Completed Research

Chapter 413 of the 2007 Acts of Assembly amended and reenacted § 32.1-162.19, relating to human research review committees, by adding a new sub-section E that states:

Each human research review committee of a state institution or agency shall ensure that an overview of approved human research projects and the results of such projects are made public on the institution's or agency's website unless otherwise exempt from disclosure under the Virginia Freedom of Information Act (i.e., § 2.2-3700 et seq.).

In compliance with this legislative mandate, the results of all completed IRB-approved research studies are listed on the IRB Internet web site by year of approval under the heading "Results of Approved Projects." The address of the IRB Internet web site is <http://www.dss.virginia.gov/about/irb.cgi>.

Appendix A

Code of Virginia Mandate

§ 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

DSS IRB Membership

DSS Institutional Review Board, 2005-09		
Name	Qualification for Service	Institutional Affiliation
Erik Beecroft, Chair	Ph.D., Economics Director of Research	Department of Social Services Division of Strategy Management & Research
Mary Disse	B.A., Psychology Post-Baccalaureate Certificate in Information Systems	Department of Social Services Division of Information Systems
Kathy Hoke	Ph.D., Mathematics Associate Dean for Research Support Director, Graduate School of Arts and Sciences	University of Richmond
Lynette Isbell	B.S., Psychology	Department of Social Services Special Asst. to Commissioner
Robert Pyndell	B.A., Business Administration Financial Analyst	Department of Social Services Office of Early Childhood Development – Child Care
James Nesmith	Doctor of Ministry (D. Min.) Urban Minister	West Broad Church of Christ Richmond, Virginia