

A Report of the
Department of Social Services
Commonwealth of Virginia

**ANNUAL REPORT ON HUMAN
RESEARCH
State Fiscal Year 11**

to the Governor and the
General Assembly of Virginia

October 2011



COMMONWEALTH OF VIRGINIA
DEPARTMENT OF SOCIAL SERVICES
Office of the Commissioner

Martin D. Brown
COMMISSIONER

October 1, 2011

MEMORANDUM

TO: The Honorable Robert F. McDonnell
Governor of Virginia

Members, General Assembly

FROM: Martin D. Brown

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 11, 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.

MDB: 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) 11 is in response to the mandate in § 63.2-218.

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Executive Summary

In SFY 11, the Department of Social Services' (DSS) human research committee, referred to as the Institutional Review Board (IRB), reviewed 4 proposed research projects. Three studies qualified for expedited review, one qualified for exempt review. In addition, three ongoing studies were each approved for one-year continuations.

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 11

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 11 (July 1, 2010 through June 30, 2011). 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 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.” Appendix A provides the full text of Section 63.2-218.

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 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, first, that the rights of clients are protected and, second, that the proposed research maintains the privacy and welfare of the participants.

Human Research Activities for SFY 11

The DSS Office of Research and Planning is responsible for administering the IRB and ensuring compliance with federal and state regulations regarding human subject research. The DSS Director of Research and Planning 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 2011 included:

- Reviewing ideas for studies and the relevant IRB regulations and requirements with the principals;
- Reviewing research protocols submitted for review and determining whether they met the criteria for IRB approval; and
- Requesting that annual Continuation Review forms be completed by principal investigators for studies planned for continuation beyond their initial one-year approval.

Projects Reviewed

Study #: 2011-01/D
Principal Investigator: Kathy L. Dial
Doctoral Student
Norfolk State University, School of Social Work
700 Park Ave.
Norfolk, VA
Title of Protocol: “The Influence of Human Capital on the Parenting Style of Grandparents Raising Grandchildren and the Well-Being of the Grandchildren in Their Care”
Date Approved: December 3, 2010
Description of Study: This descriptive, cross-sectional research identifies three independent human-capital variables – educational attainment, occupation, and income; three intermediate variables describing parenting styles – authoritarian, authoritative, and permissive; and three dependent child well-being variables – academic achievement, negative behavior (e.g., poor peer relationships, conduct disorder), and pro-social behavior. The study will address four theoretical questions: (1) How does human capital influence the parenting style of grandparents raising grandchildren? (2) How does the grandparent’s parenting style influence the grandchild’s well-being? (3) Is there a correlation between the parenting styles of grandparents raising grandchildren and the parenting styles used with their children? (4) How do human-capital factors and the parenting styles of grandparents raising grandchildren influence the grandchild’s well-being?

The IRB approved the research in an expedited review and required the Principal Investigator to submit a “Request for Review and Clearance” form, sign the “Assurance of Confidentiality” form, provide copies of the three in-person questionnaires to be administered to the grandparents agreeing to participate in the study, and a copy of the Informed Consent form she plans to use with the participating grandparents.

Study #: 2011-02/B
Principal Investigator: Isabel Bradburn, Ph.D.
Research Director
Child Development Center, 358 Wallace Hall
Department of Human Development (MC 0416)
Virginia Tech, Blacksburg, VA 24061-0461
Title of Protocol: “An Evaluation of Virginia’s Family Star Quality Initiative Pilot”
Date Approved: December 14, 2010
Description of Study: This evaluation is both a formative and process evaluation of the extension of the Virginia Star Quality Initiative (VSQI) to family child care providers, funded through a contract with the VDSS Division of Child Care and Early Childhood Development. The pilot runs from October 1, 2010 through July 31, 2011. Data collected will be based upon extensive observations of family child care homes and

focus on VSQI procedures and the fidelity of training and field ratings to these procedures. While collecting some data on the background and characteristics of raters and mentors, for future training purposes, the evaluator will conduct focus group and telephone interviews with employees (i.e., raters, mentors, local coordinators) and providers (i.e., pilot participants). Primary source documents to be reviewed include four: (1) descriptions of training modules and the procedures for raters, (2) surveys, on-line and paper, (3) telephone interviews with family care providers and stakeholders, and (4) focus groups with separate groups of stakeholders (i.e., raters, mentors, local coordinators, and family care providers). The primary purpose of the evaluation is to help both the developers and managers of VSQI learn as much as possible about the implementation of the family child care portion of the Star Quality Initiative, to improve and sustain it as a productive initiative of the overall Virginia Star Quality Initiative.

The IRB approved the Evaluation and protocol as exempt from further review since it involves observations and gathering information from documents already available publicly. The Board required the Principal Investigator to fill out the Exemption Review form, sign an “Assurance of Confidentiality,” and provide a copy of the Evaluation Plan and protocol previously submitted to the Virginia Tech IRB as well as the “Request for Review and Clearance” for the review.

Study #:	2011-03/M
Principal Investigator:	Karin Malm Senior Research Scientist Child Trends, Inc. 4301 Connecticut Ave., N.W., Suite 350 Washington, D.C. 20008
Title of Protocol:	“An Exploratory Study of Foster Care Diversion Practices in the Commonwealth of Virginia”
Date Approved:	December 21, 2010
Description of Study:	In this exploratory study, Child Trends will carry out two-day visits to six Virginia localities to conduct semi-structured interviews and focus groups, to explore and document the themes involving policies and practice regarding diversion from foster care. Those interviewed will be DSS child-welfare staff, community providers, court staff, kinship caregivers, and birth parents of children who have been diverted already. The purpose of the study is to examine when and how public agencies use relatives and other natural connections to care for children unable to remain safely in their own homes in order to prevent them from entering foster care.

The IRB approved this exploratory research and protocol in an expedited review. It required the submission of the “Request for Review and Clearance,” signed copies of the “Assurance of Confidentiality” by the three individuals who will have access to confidential data; and the research design and protocol for the study, including planned protocols for interviews and focus group sessions. The research is being underwritten by the Annie E. Casey Foundation. Child Trends is a professional research organization that has developed its own IRB requirements that conform to those of the U.S. Department of

Health and Human Services, Office of Human Research Protections, and the U.S. Department of Education, National Center on Educational Statistics.

Study #: 2011-04/E-P
Principal Investigator: Paul Estabrooks and Serena L. Parks
Professor and Doctoral Student, respectively
Human Nutrition, Foods, and Exercise
Translational Obesity Research Program
Integrated Life Sciences Building (CRC), Room 1037
Virginia Tech
1981 Kraft Drive
Blacksburg, VA 24061

Title of Protocol: “Assessing Lifestyles to Foster Healthy Living and Integrating Healthful Eating and Physical Activity Skills into the Foster Care System: A Delphi Study.”

Date Approved: June 10, 2011

Description of Study: In these combined studies targeting childhood obesity, the investigators will assess the current eating and physical activities of foster children and their providers and, also, determine the relationship with the home environment – given the demonstrable relationship between these two functions. The results will be used to inform researchers and practitioners, including their associations, about the need for interventions targeting foster children and their providers.

The IRB approved this doctoral research and protocol in an expedited review. It required the submission of the approved Virginia Tech IRB Research Protocol form, which incorporated the research designs and protocols for the combined studies, and a signed copy of the “Assurance of Confidentiality” by the two individuals with access to confidential data.

Continuation Reviews and Modifications

Three ongoing studies were approved in Continuation Reviews, one that began in SFY 2008 and two that began last fiscal year. One of the two studies approved in SFY 2010 has six local sites, four of which were due for reviews this year – three in SFY 2011 and one shortly after the start of SFY 2012, in July 2011.

- (1) “Evaluation Plan: VA Infant and Toddlers Specialist Network,” Sheri Osborne, Child Development Resources, Norge, VA, Sept. 2, 2010, covering evaluation activities through September 1, 2011;
- (2) “Building Community-Level Social Capital,” Kevin W. Allison, Ph.D., Principal Investigator, October 20, 2010, covering research activities through October 19, 2011; and
- (3) “Pilot Communities Projects (6): Infants/Toddlers and the Development of Community Resources,” covering activities continuing between April 20, 2011 and July 13, 2011, covering pilot activities through July 12, 2012.

Significant Changes to Approved Projects

There were none to report.

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, design issues, 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>. Results from studies initiated in SFY 2005 through SFY 2010 are available.

Periodic Review: Human Subject Research Regulations, Virginia Administrative Code

Section 63.2-218 of the Code of Virginia (Code) requires periodic (i.e., every four-year) public review of the primary regulation – 22 VAC 40-890, Human Subject Research Regulations – that provides the basis on which the Department of Social Services reviews and approves research involving human subjects. The required review was published in the Virginia Register of Regulations on June 6, 2011, with public comments received through June 27. A summary of the periodic review, for which no comments were received, was prepared for the August 2011 meeting of the State Board of Social Services, for approval.

Subsequent to the State Board's approval of the existing regulation, we corrected the definition of "local department" in the regulation to conform it to Code (i.e., Section 63.2-100, where "local department" means "*the local department of social services of a county or city in this Commonwealth*"). On advice of the Office of the Attorney General, under Section 2.2-4006 A 4a, regulations being amended for the sole purpose of conforming them to Code are exempt from the Administrative Process Act. The corrected definition was published in the Virginia Register of Regulations for 30 days and, then, became effective as part of the regulation in the "definitions" section, 22 VAC 40-890-10. Definitions.

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

VDSS Institutional Review Board, 2005-10		
Name	Qualification for Service	Institutional Affiliation
Erik Beecroft, Chair	Ph.D., Economics Director of Research	Department of Social Services Organization Development
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
Robert Pyndell	B.A., Business Administration Financial Analyst	Department of Social Services Division of Child Care and Early Childhood Development
James Nesmith	Doctor of Ministry (D. Min.) Urban Minister	West Broad Church of Christ Richmond, Virginia