

A report of the
Department of Social Services
Commonwealth of Virginia

**ANNUAL REPORT
ON HUMAN RESEARCH
State Fiscal Year 2008**

to the Governor and the
General Assembly of Virginia

October 2008



COMMONWEALTH OF VIRGINIA
DEPARTMENT OF SOCIAL SERVICES
Office of the Commissioner

Anthony Conyers, Jr.
COMMISSIONER

October 1, 2008

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 2008, 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/lrm

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) 08 is in response to the mandate in § 63.2-218.

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Executive Summary

In SFY 08, 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, there were two annual continuation reviews of previously approved studies.

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 08

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 08 (July 1, 2007 through June 30, 2008). 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 08

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 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 08 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 already underway.

Projects Reviewed

Study #: 2008-01/A
Principal Investigator: Kevin Allison, Ph.D.
College of Humanities and Sciences
Virginia Commonwealth University
Title of Protocol: “Building Community-Level Social Capital”
Date Approved: August 14, 2007; amended October 19, 2007
Description of Study: This study is based on the hypothesis that increasing community-level social capital for youth will reduce youth risk for violence and adolescent pregnancy. It focuses on the development of community-based strategies to support youth and their families in the target age group (i.e., early adolescence through emerging adulthood) by: (1) building supportive relationships among neighbors in high-risk communities; (2) supporting information exchanges that allow families access to information about positive youth-development resources in the community; (3) supporting families by providing access to referral information for services targeting high-risk youth and parents experiencing stress or depression; (4) developing contextually appropriate conflict resolution skills; and (5) increasing self efficacy for the use of contraceptives.

The IRB approved this study on an expedited basis after receiving project agreement to meet specified confidentiality and data safety conditions raised during DSS review. These conditions included having the Data Manager and Director of Research Operations sign separate copies of the Assurance of Confidentiality and providing a plan for destroying identifying DSS client information as soon as the study is finished with it, as part of the “Data and Safety Monitoring” section of their protocol.

Study #: 2008-02/T
Principal Investigator: Paul Trampe
Ph. D. Candidate
George Mason University, School of Public Policy
Title of Protocol: “Survey of Food Stamp Recipients in Virginia Concerning Responses to Marginal Tax Rates”
Date Approved: September 4, 2007
Description of Study: This study will survey Food Stamp recipients at selected local departments of social services, with the consent of their directors, to attempt to discover what, if any, effect the income-based reduction in public assistance (e.g., Medicaid, public housing) has on recipients’ efforts/willingness to work. All survey results will be compiled statistically and reported in the aggregate.

The IRB approved this research on an expedited basis, since it had already been approved by the George Mason University Human Subjects Research Review. The Principal Investigator was required to complete and sign the Assurance of Confidentiality and the Request for Review and Clearance of Human Subjects Research forms prior to approval.

Study #: 2008-03/O
Principal Investigator: Sheri Osborne
Director of Training
Child Development Resources, Norge, VA
Title of Protocol: “1-2-3 READ! Virginia Evaluation Plan”
Date Approved: January 17, 2008
Description of Study: For a one and one-half year period, the 1-2-3 READ! Early Literacy Training Program will provide training to approximately 600 infant and toddler teachers throughout Virginia in the use of the 1-2-3 READ! curriculum, proven to result in pre-school children achieving significant, measurable gains in their language and cognitive development. During this period, these infant and toddler teachers will have the opportunity to receive training, supportive curriculum modules, and early literacy materials. In addition, among the 600 teachers trained, approximately 200 of their programs will receive on-site coaching to assist the teachers further in implementing 1-2-3 READ! in the home setting. Child Development Resources, a private non-profit, community-based agency, has won national recognition for its innovative models of training professionals who serve children from birth to age 8 and their families.

The IRB approved this pre-school training and evaluation plan as exempt from further review since it will be conducted in established educational settings and it involves the use of educational tests, survey/interview procedures, and observation to evaluate the effects of the training on the teachers trained in the 1-2-3 READ! curriculum. The Principal Investigator signed the Assurance of Confidentiality form.

Continuation Reviews

In addition to the three SFY 08 project reviews noted above, two ongoing projects were required to complete annual Continuation Review forms during the fiscal year, and did so:

- (1) “Workload Standards Update for Local Departments of Social Services,” Hornby Zeller Associates, Inc.; Dennis Zeller, Ph.D., Principal Investigator, filed June 20, 2008; and
- (2) “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 June 20, 2008.

Significant Changes to Approved Projects

In October of 2007, the Virginia Commonwealth University study, “Building Community-Level Social Capital,” requested a change to the August 14, 2007 IRB-approved research protocol. The change consisted of three amendments, all of which were approved by the IRB, using expedited review, on October 19, 2007. The amendments:

- (1) Added measures to assess parental sense of family and neighborhood cohesion, as well as parental coping behaviors with adolescence and adolescents;

(2) Modified the Consent Form (for adults) and the Assent Form (for their children) to translate the forms into Spanish for participants whose first or preferred language is Spanish; and

(3) Allowed families who are unable to speak English to complete a shortened form of the survey instrument in Spanish, supported by a trained interviewer.

IRB Meetings

The IRB did not hold a meeting of the full board during the fiscal year. Subsets of IRB members, however, met several times during the year to discuss individual studies requiring review, modification, or the application of federal or 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.

Appendix B

DSS IRB Membership

VDSS Institutional Review Board, 2005-08		
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
Cynthia Holdren	Master's in Public Administration Manager, Management Services Unit	Department of Social Services, Division of Child Support Enforcement (retired, Spring 2008)
Lynette Isbell	B.S., Psychology Director	Department of Social Services, Division of Family Services
Robert Pyndell	B.A., Business Administration Financial Analyst	Department of Social Services, Office of Early Childhood Development – Child Care
James Nesmith	M. Div. Urban Minister	West Broad Church of Christ Richmond, Virginia

