

A Report of the
Department of Social Services
Commonwealth of Virginia

**ANNUAL REPORT ON HUMAN
RESEARCH
State Fiscal Year 2012**

to the Governor and the
General Assembly of Virginia

October 2012

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) 2012 is in response to the mandate in § 63.2-218.

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Executive Summary

In SFY 2012, the Department of Social Services' (DSS) human research committee, referred to as the Institutional Review Board (IRB), reviewed two (2) proposed research projects. One study qualified for expedited review, and one qualified as exempt from review. In addition, two 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 2012

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 2012 (July 1, 2011 through June 30, 2012). 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 2012

The DSS Office of Research and Planning (ORP) 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, Erik Beecroft, PhD, serves as chair of the IRB, and a senior research associate (Gail Jennings, PhD) coordinates administration of the IRB and proposal reviews.

Major activities in support of the IRB for SFY 2012 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.
- Updating the IRB manual and forms posted on the VDSS web site.

Ms. Jennings, who came to the agency in January 2012, assumed the role of Coordinator for the IRB. In June 2012, she was appointed by the Commissioner to serve as Co-Chair for the IRB in addition to her duties as IRB Coordinator, effective July 1, 2012. Mr. Beecroft will continue to serve on the IRB as a Co-Chair and assist Ms. Jennings with IRB activities.

The State Board of Social Services human research regulation requires that IRB members “ensure the competent, complete, and professional review of human research.” Since the previous IRB members’ appointments had lapsed as of July 1, 2011, the IRB as a group has not met during the past two fiscal years. In June 2012, the Commissioner of VDSS appointed a new board consisting of nine members (including Mr. Beecroft and Ms. Jennings) to serve a term of three years (2013-2015), which are effective July 1, 2012. Six new members were appointed. Five appointed members represent various divisions and expertise of the Department (including the local social services departments), and bring a wealth of knowledge and experience related to VDSS programs and constituents. Additionally, regulation requires that at least two members hold no affiliation with the Department. Four individuals are members of the community-at-large, including one member whose agency serves the homeless and one member whose agency serves unemployed and underemployed individuals who are likely to be benefit recipients. Two new members also bring previous IRB experience from other agencies. The 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 organizational affiliation for each IRB member who will serve in the 2013-2015 term. The IRB Coordinator will convene the Board in September or October 2012 to provide an orientation to new members and provide an update on the status of IRB activities for all members.

The agency IRB renewed its registration with the U.S. Department of Health and Human Services’ Office for Human Research Protection (OHRP). The registration is effective for the next three years (through May 2015). Furthermore, the agency renewed its status as an organization conducting human research (Federal-Wide Assurance) with OHRP. The agency’s FWA registration expires in June 2017.

Projects Reviewed

There were two projects reviewed in SFY 2012.

Study #: 2012-01K
Principal Investigator: Mark D. Kilgus, MD, PhD, Chair
Virginia Tech, Carilion School of Medicine
Department of Psychiatry and Behavioral Medicine
(Carilion Clinic)
2 Riverside Circle
Roanoke, VA
Title of Protocol: “Respite to Enable Permanent Placement for Children with Reactive Attachment”
Date Approved: November 29, 2011
Description of Study: The purpose of this research is to learn how to best help children in foster care suspected of having Reactive Attachment Disorder (RAD) adjust to their foster home in order to minimize placement disruptions. Study participants were children and youth ages six to 16 years in the care of the Roanoke City Department of Social Services. Children and youth were referred into the study on the basis of review of DSS records and analysis of questionnaire responses from previous and current foster parents/guardians. (The PI also conducted a psychiatric assessment to confirm the diagnosis of reactive attachment.) Using a randomized control design, participants were randomly assigned to either a control group or a treatment group. The control group received the current normal interventions as practiced by DSS; the treatment group received regularly scheduled planned respite care by screened volunteer families, who were also recruited for this study and trained using the PRIDE (Parent Resources for Information, Development, and Education) curriculum. Both youth and families were asked to complete monthly rating scales as well as Child Behavior checklists at the beginning and end of the study period. The hypotheses tested were that the respite care intervention would reduce the number of prospective placement disruptions and the intensity of disruptive behaviors over an 18-month period. Although unlikely, trained mental health professionals were available for consultation and intervention, if adverse outcomes occurred. The risk of participating in the study was minimal for youth and volunteer families.

The IRB approved the research in an **expedited** review and required the Principal Investigator to 1) modify the explanation form for foster parents to include a signature line, 2) revise the script for children to allow child participants to ask questions, and 3) either modify the child script or develop a form that will allow children to provide assent in this study. Furthermore, the PI was asked to submit a signed “Assurance of Confidentiality”.

Study #: 2012-02S
Principal Investigator: Medical Home Plus
Title of Protocol: “Medication Administration Training (MAT) Program Evaluation”
Date Approved: July 22, 2011
Description of Study: Child care providers who work in licensed or regulated child day programs and who give prescription medications to children are required by the *Code of Virginia* to satisfactorily complete the MAT course. The MAT is a competency-

based course approved by the Board of Nursing (BON) and Virginia Department of Social Services (VDSS) to train providers who work in child day programs to safely administer medication to children. The MAT course must be facilitated by an approved MAT Trainer. This study is an evaluation of the effectiveness of the MAT program, conducted by Medical Home Plus. The evaluation study qualified for **exemption** on the basis that it is taking place in an educational setting.

Continuation Reviews and Modifications

Two ongoing studies, which both originated in SFY 2010, were approved in Continuation Reviews.

- (1) “The Influence of Human Capital on the Parenting Style of Grandparents Raising Grandchildren and the Well-Being of the Grandchildren in Their Care” (PI: K. Dial, PhD candidate, Norfolk State University) – Modification to grandparent questionnaire and addition of a resource guide, approved on 8/3/2011; study activities approved through 8/2/2012. (Note: The PI has completed data collection and will be defending her dissertation study in August 2012. Summary findings will be forthcoming and published on the VDSS IRB web page.)
- (2) “Risky Relationships and Teen Dating Violence Among High-Risk Adolescents“ (PI: N. Dickon Reppucci, Ph.D., University of Virginia Department of Psychology) – Continuation and minor modifications to study’s consent forms and questionnaires, approved on May 1, 2012; study activities approved through April 30, 2013.

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. The IRB Chair and the IRB Coordinator met to discuss individual proposals requiring review, design issues, or application of federal and state regulations to specific-related issues.

As mentioned earlier, the new IRB will hold its first meeting in September/October of 2012. The purpose of the meeting will be to provide an orientation to IRB procedures and practices for new members and update all members on IRB activities and developments.

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. One study -- "1-2-3 Read! Virginia" (PI: Sheri Osborne, Child Development Resources), which originated in FY 2009 -- was completed in FY 2012. A summary of findings for this study are in Appendix C.

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 (2013-2015)

DSS Institutional Review Board, 2013-2015		
Name	Qualification for Service	Institutional Affiliation
Erik Beecroft (Co-Chair)	Ph.D., Economics Director of Research & Planning	Virginia Department of Social Services Division of Organizational Development, Research and Planning
Gail Jennings (Co-Chair & Coordinator)	Ph.D., Psychology Senior Research Associate	Virginia Department of Social Services Division of Organizational Development, Research and Planning
Mary Disse	B.A., Psychology Business Analyst Post-Baccalaureate Certificate in Information Systems	Virginia Department of Social Services Division of Information Systems
Jennifer Behrens	M.S.W.; Ph.D. candidate (Public Policy and Administration) Program Manager, Outcome- Based Reporting and Analysis Unit (OBRA)	Virginia Department of Social Services Division of Family Services
Erika Jones-Haskins	M.S.W. Director of Program Initiatives	Homeward, Program Initiatives
Susan K. Spain	M.S. Senior Research Assistant	Virginia Commonwealth University Department of Family Medicine
Greg Stolcis	Ph.D., Public Policy and Administration Adjunct Faculty (VCU)	Virginia Commonwealth University Wilder School of Government and Public Affairs
Tamara Temoney	Ph.D., Public Policy and Administration Assistant Agency Director	Hanover County Department of Social Services
Najmah Thomas	Ph.D., Public Policy and Administration Policy Planning Specialist	Virginia Community College System

Appendix C: Summary of Study Findings

1-2-3 READ! Virginia. The Virginia Department of Social Services (VDSS), Division of Child Care and Early Childhood Development, had a sole source contract with Child Development Resources to implement the 1-2-3 READ! Virginia training program (www.123read.cdr.org). The contract period was August 1, 2010 through December 31, 2011. The purpose of the 1-2-3 READ! Virginia training program was to increase Virginia's infant and toddler teachers' knowledge and skills to enhance the language and early literacy skills of young children from birth to 36 months. Early literacy trainer coaches under this contract and infant and toddler specialists from the Virginia Infant & Toddler Specialist Network served as co-trainers to offer the training component of this program.

Major activities included:

- providing 19 two-day training sessions to 550 infant and toddler staff from 328 programs throughout the state on the use of 1-2-3 READ!, a research-based storybook early literacy curriculum;
- providing participants of the training *The Guide for Using the 1-2-3 READ! Curriculum*, three complete curriculum modules (module booklet, focal book and supplemental children's books), a module booklet and focal book, two resource books, a board book, a sample take-home bag, a CD, and an opportunity to apply for follow-up on-site coaching and additional literacy materials;
- conducting 268 on-site coaching visits with 58 programs serving infants and toddlers for a total of 957.75 hours (679 hours on-site, 278.75 hours preparation and follow up); and
- providing programs participating in on-site coaching with age-appropriate toys, dramatic play props, art supplies, and books that corresponded to the curriculum modules staff received during the training.

Results of the two-day training indicated:

- participants increased their knowledge of early literacy by 14.1% (pre- and post-training measure consisting of 20 multiple-choice questions);
- participants rated their proposed use of knowledge to improve literacy services as 4.81 on a 5 point scale with five being high; and
- participants rated the overall quality of the trainings as 4.85 on a 5 point scale with five being high.

Results of the on-site coaching visits indicated:

- an overall increase in use of 1-2-3 READ! strategies from 2.75 to 3.50 (pre- and post-coaching as measured by the "Infant/Toddler Environmental Observation Instrument" that consists of five areas for evaluation using a Likert Scale with 1 = almost none and 4 = numerous); and
- an overall quality rating of 4.90 on a 5 point scale with 5 being high (participants' completion of evaluation forms).