



COMMONWEALTH of VIRGINIA
DEPARTMENT OF SOCIAL SERVICES
Office of the Commissioner

Margaret Ross Schultze
COMMISSIONER

October 1, 2016

MEMORANDUM

TO: The Honorable Terence R. McAuliffe
Governor of Virginia

Members, Virginia General Assembly

FROM: Margaret Ross Schultze

A handwritten signature in blue ink, reading "Margaret Ross Schultze".

SUBJECT: Report on Human Research

I am pleased to submit the Department of Social Services' annual report on human research activities pursuant to § 63.2-218 of the Code of Virginia. If you have questions or need additional information concerning this report, please contact me.

MRS:kc

Attachment

ANNUAL REPORT ON HUMAN RESEARCH
State Fiscal Year 2016

October 2016

A Report of the
Department of Social Services
Commonwealth of Virginia

to the Governor and
General Assembly of Virginia

Table of Contents

EXECUTIVE SUMMARY	II
REPORT MANDATE	1
BACKGROUND	1
SFY 2016 ADMINISTRATIVE ACTIVITIES OF THE IRB.....	2
IRB REVIEW OF RESEARCH, SFY 2016	3
Study Title: Examination of DSS Benefits Use Among FY 14 Cohort of Students Enrolled in Non-credit Coursework at the Virginia Community College System (VCCS)	4
Study Title: Fairfax County Department of Family Services Customer Satisfaction Survey	5
Study Title: Assessing the Barriers that Constrain the Adequacy of SNAP Allotments (SNAP Barriers Study); Short Name: The Food and Your Household Study.....	6
Study Title: Virginia Family Partnership Survey (FPM) Survey	7
Study Title: Project Social Emotional Education & Development (SEED) Evaluation.....	8
Study Title: The Evaluation of SNAP Employment and Training Pilots.....	9
Study Title: Impact of Burnout, Compassion Fatigue, and Vicarious Trauma Among Child Protective Services Workers.....	10
Study Title: National Food Study Pilot	11
Study Title: The Evaluation of Food Insecurity Nutrition Incentives (FINI) Grants	12
Study Title: Evaluation of Demonstration Projects to End Childhood Hunger (EDECH)	13
<i>Continuing Reviews</i>	14
Study Title: Wendy's Wonderful Kids Post-Adoption Study: How are adopted foster youth faring as young adults?.....	14
Study Title: Virginia Infant and Toddlers Specialist Network.....	15
<i>Significant Changes from Research Proposals as Approved by the IRB</i>	16
Study Title: Project Social Emotional Education & Development (SEED) Evaluation....	16
<i>Results of Closed Studies</i>	17
Study Title: Impact of Burnout, Compassion Fatigue, and Vicarious Trauma Among Child Protective Services Workers.....	17
Study Title: Fairfax County Department of Family Services Customer Satisfaction Survey	18
Study Title: Mind the Gap: An Assessment of Needs in the Hampton Roads Bhutanese Refugee Community.....	19
CONCLUSION	21
APPENDIX A: VDSS IRB MEMBERSHIP.....	A-1
APPENDIX B: MINUTES OF EACH IRB MEETING.....	A-1

Executive Summary

This report on human research studies reviewed and approved by the Virginia Department of Social Services' (VDSS) human research committee is in response to the mandate in section 63.2-218 of the Code of Virginia.

Research involving VDSS clients generally involves minimal risk observational, behavioral or opinion studies. The potential risk for these types of studies most often involves issues of client privacy, confidentiality and, to a lesser extent, psychological harm (for example, from surveys that include sensitive questions). It is the role of the human research committee, known as the Institutional Review Board (IRB), to ensure proposed studies will be conducted in accordance with federal and state regulatory requirements governing human research.

During SFY 2016, 10 studies were submitted for approval to the VDSS IRB.

1. Two minimal risk studies were reviewed at convened IRB meetings. Of those, one was approved. The other study was tabled by the VDSS IRB and subsequently, the United States Department of Agriculture suspended the study before the IRB could take final action (Study # 2016-03).
2. Eight studies were reviewed by the IRB Chair and/or at least one other board member. Of those, two were closed without IRB action (SFY 2016-01 & SFY 2016-10), five survey studies were approved by exempt review and one study was tabled because it requires revisions to the consent process. The investigator was notified in writing of the modifications required to secure IRB approval.

Of the two studies closed without IRB action, study number SFY 2016-01 was a request for access to client identifiable data. The proposed study did not directly relate to administration of the Temporary Assistance for Needy Families (TANF) program. Thus, the data request was inconsistent with the Code of Virginia (§ 63.2-102) which limits the disclosure of client information to purposes directly related to the administration of each program. The second study closed without IRB action was the evaluation of the Child Nutrition Hunger Demonstration Project (Virginia 365 Project). The evaluation organization determined that access to client Supplemental Nutrition Assistance Program (SNAP) data was not essential to the evaluation of the 365 demonstration project.

The Chair convened the IRB four times during the fiscal year. The first meeting concerned violation of the terms of study approval (Study # 2014-06). Two of the remaining three meetings were for initial review of proposed research and the fourth meeting was to re-consider a previously tabled initial review.

Annual Report on Human Research October 2016

Report Mandate

The Code of Virginia¹ requires 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 documents State Fiscal Year (SFY) 2016 activities of the Virginia Department of Social Services (VDSS) human research committee, known as the Institutional Review Board (IRB). The IRB is charged with reviewing, approving, and monitoring research conducted or authorized by VDSS, local departments of social services, VDSS contractors, and VDSS-licensed facilities.

Background

Typically, research submitted to the IRB involves social or behavioral studies or evaluations of programs and services the agency provides to clients. Physical risk of harm is unlikely for these types of studies or evaluations. Most often, potential risks are associated with issues of privacy, confidentiality, equitable treatment, and/or client informed consent.

The IRB reviews research prior to implementation to ensure, first, that the rights of clients are protected and, second, that the proposed research maintains the privacy and confidentiality of the participants. Using established criteria² for IRB approval of research, the IRB may determine that a study satisfies criteria for an exempt review, is appropriate for expedited review, or requires full board review. Typically, exempt and expedited reviews are independently conducted by one or two members of the IRB. In a full review, the IRB is convened and the research must be approved by a majority of its members.

Since 2006, VDSS has committed to the U.S. Department of Health & Human Services (HHS) that it will comply with requirements set forth in the regulations³ for the protection of human subjects participating in research. Compliance, known as the “FederalWide assurance,” is a necessary condition for VDSS to receive federal grants that may involve human research activities. Among other things, the terms of the assurance requires VDSS to operate an IRB. VDSS’ current “FederalWide Assurance” (#FWA00010976) must be renewed no later than July 22, 2020 and the agency’s HHS registration (# IORG0004422) of its IRB must be renewed no later than March 11, 2019.

The VDSS Division of Research and Planning is responsible for administering the IRB and ensuring compliance with federal and state regulations regarding human subject research. Myra G. Owens, PhD, serves as the IRB administrator and chair. She was appointed to these roles July 1, 2015. Cumulatively, she has 15 years’ experience serving as IRB chair, IRB member or

1 Section 63.2-218

2 22VAC40-890 et seq.; & 45 CFR 46 et seq.

3 45 CFR 46.103

research regulatory coordinator at Virginia state agencies and at Virginia Commonwealth University.

Currently, the IRB is composed of 11 members. Each member is appointed by the VDSS Commissioner and generally serves a three-year term. IRB membership complies with state and federal human research regulations. A roster of current members is located in Appendix A.

Most applications are reviewed using the “primary reviewer” method. Specifically, reviews are independently conducted by the IRB Chair and at least one other board member. This method is most appropriate because the vast majority of applications qualify for exempt or expedited review. The primary reviewer method conserves resources by minimizing the need for convened meetings.

The Chair convened the IRB four times during SFY 2016. One meeting concerned violation of the terms of research approval (Study # 2014-06). Two meetings concerned initial review of proposed research (SFY 2016-03 & SFY 2016-06) and one meeting was a re-consideration of a previously tabled initial review (SFY 2016-06).

SFY 2016 Administrative Activities of the IRB

1. Recommended IRB language for contracts and data use agreements that involve human research activities.
2. Disseminated IRB awareness information to VDSS divisions.
3. Initiated policy, procedures, and forms updates to ensure concordance with the terms of the “Federalwide Assurance.”
4. Provided input and feedback for proposed research and evaluation studies.
5. Reviewed 10 proposed research studies.
6. Reviewed two requests from principle investigators (PIs) for continuation of studies beyond their initial one-year approval.
7. Informed IRB members about procedural changes via e-mail correspondence and convened meetings.
8. Maintained a database for tracking the status of IRB reviews, study modifications, and continuations.
9. Updated and maintained the IRB public web page. (<http://www.dss.virginia.gov/about/irb.cgi>). The web page is the public face of the IRB and provides access to forms, procedures, annual reports, resources, and results of approved projects.

IRB Review of Research, SFY 2016

During SFY 2016, 10 studies were submitted for IRB consideration.

1. Two minimal risk studies were reviewed at convened IRB meetings. Of those, one was approved (Study #: 2016-06). The United States Department of Agriculture suspended the other study before the IRB could take final action (Study #: 2016-03).
2. Seven studies were finalized using the primary review process; specifically, reviews were conducted by the IRB Chair and/or at least one other board member. Of those, two were closed without IRB action (SFY 2016-01 & SFY 2016-10) and five survey studies were approved by exempt review (Study #: 2016-02, 2016-04, 2016-05, & 2016-07).
3. As of this report, one study was tabled because it requires revisions to the consent process (Study # 2016-08). The investigator was notified in writing of the modifications required to secure IRB approval.

A summary presentation of each study is provided in the next section of this report. Studies are presented in the order in which the IRB received the initial review application.

Study Title: Examination of DSS Benefits Use Among FY 14 Cohort of Students Enrolled in Non-credit Coursework at the Virginia Community College System (VCCS)

Study #	2016-01
Principal Investigator (PI)	Lori Dwyer, M.S.
PI Affiliation	Virginia Community College System
IRB Review Type	Primary Reviewer
IRB Decision & Date	<p><i>No IRB action taken, application returned to PI along with a letter of explanation.</i></p> <p>The Code of Virginia (§63.2-102) limits the disclosure of client information to purposes directly related to the administration of each program. The proposed study did not directly relate to administration of the Temporary Assistance for Needy Families (TANF) program, Virginia Initiative for Employment not Welfare (VIEW) program or the Supplemental Nutrition Assistance Program. February 19, 2016</p>
Status as of June 30, 2016	IRB application closed and returned to PI
Study Description	<p>The purpose of this study was to construct a profile of State Fiscal Year 2014 Virginia Community College System (VCCS) students enrolled in non-credit coursework (N = 17,604). The profile was intended to support implementation of the VCCS strategic plan.</p> <p><u>Proposed VDSS Role:</u> Upon receipt of VCCS student identifiers, VDSS would match student identifiers to TANF, VIEW and SNAP client information and provide TANF, VIEW and SNAP client identifiable data to the VCCS.</p>

Study Title: Fairfax County Department of Family Services Customer Satisfaction Survey

Study #	2016-02
Principal Investigator (PI)	James M. Ellis, PhD.
PI Affiliation	Center for Survey Research (CSR), University of Virginia
IRB Review Type	Exemption Category 2, survey procedures; 45 CFR 46.101(b)(2)
IRB Decision & Date	Approved, August 28, 2015
Status as of June 30, 2016	2015 survey completed as of January 2016. Study findings are posted to the VDSS IRB web page. Also, see Page 18 of this report for study findings.
Study Description	<p>CSR will use the questionnaire developed for DFS in June 2005 as the data collection instrument for the 2015 client satisfaction survey. The survey was administered by mail with follow-up by telephone to improve survey response rates. The goal was to achieve a sample sufficient for analysis of survey responses for the following four divisions of DFS: Adult and Aging, Children, Youth and Families, Office for Children and Self-Sufficiency.</p> <p><i>Funding Source:</i> Fairfax Department of Family Services (DFS); contract #4400000055</p>

Study Title: Assessing the Barriers that Constrain the Adequacy of SNAP Allotments (SNAP Barriers Study); Short Name: The Food and Your Household Study

Study #	2016-03
Principal Investigator (PI)	Mustafa Karakus, Ph.D.
PI Affiliation	Westat
IRB Review Type	Full Board
IRB Decision & Date	On September 17, 2015, the study was tabled because the IRB needed additional information in order to complete its review. Subsequent to the VDSS action to table the study, the USDA FNS suspended the study.
Status as of June 30, 2016	Study suspended by the USDA
Study Description	<p>Westat will conduct a study among Supplement Nutrition Assistance Program (SNAP) participants to identify the major individual, household, and environmental barriers affecting the household's perceived ability to have access to a healthy diet. Information gained from the study will be used by the United State Department of Agriculture, Food and Nutrition Service to determine how, if at all, these barriers can be accounted for in determining SNAP allotments.</p> <p><i>Study Methods</i> will include: 1) A mail survey, with telephone follow-ups which will be sent to approximately 4,800 heads- of- households across 30 states. 2) An in-home interview of 120 heads-of-households selected from the pool of individuals who completed the survey.</p> <p><i>VDSS Role:</i> VDSS will provide personally identifiable data (names, addresses, phone numbers, case file household size, number of children under the age of 18, latest uninterrupted benefit start date, and monthly amount of SNAP benefit) to Westat for every adult head-of-household receiving SNAP as of July 31, 2015.</p> <p><i>Funding Source(s):</i> Food and Nutrition Service, United State Department of Agriculture (USDA Contract # AG-3198-D-14-0071)</p>

Study Title: Virginia Family Partnership Survey (FPM) Survey

Study #	2016-04
Principal Investigator (PI)	Gail Jennings, PhD
PI Affiliation	VDSS, Office of Research and Planning
IRB Review Type	Exemption 2, survey procedures; 45 CFR 46.101(b)(3)
IRB Decision & Date	Approved; November 3, 2015
Status as of June 30, 2016	Pilot completed April 29, 2016. Planning process underway for broader implementation
Study Description	The primary purpose of this <u>anonymous</u> online pilot survey is to assess satisfaction with Family Partnership Meeting (FPM) meetings and to determine level of engagement in partnership meetings. Prospective survey participants are clients of local departments of social services' FPM participants. Five local departments participated in the pilot study.

Funding Source: VDSS

Study Title: Project Social Emotional Education & Development (SEED) Evaluation

Study # 2016-05

Principal Investigator (PI) Susan Murdock, PhD

PI Affiliation Partnership for People with Disabilities, Virginia Commonwealth University

IRB Review Type Exemption Category 2, survey procedures; 45 CFR 46.101(b)(2). This approval has no expiration date and no requirement for continuing review as long as there are no changes to study procedures.

IRB Decision & Date Approved, January 13, 2016

Status as of June 30, 2016 Ongoing.

Study Description The proposed study is a training effectiveness and outcomes evaluation of professional development activities that will be provided to child care professionals. Professionals provide infant and toddler care throughout the Commonwealth of Virginia.

Methods: Study will make use of interviews, pre/post knowledge tests, training satisfaction surveys, interviews, and records review.

VDSS Role: Provided funding for the conduct of the training and the evaluation of training. There is no specific intent to involve VDSS clients in research activities.

Funding Source(s): Virginia Department of Social Services, Memorandum of Agreement Contract Number CECD-13-003; Titled: Professional Development for Child Care Providers on Social Emotional Development of Infants and Toddlers

Study Title: The Evaluation of SNAP Employment and Training Pilots

Study #	2016-06
Principal Investigator (PI)	Michael Ponza
PI Affiliation	Mathematica Policy Research
IRB Review Type	Full Board
IRB Decision & Date	Approved; February 11, 2016
Status as of June 30, 2016	Ongoing; four modifications approved during the SFY
Study Description	<p>Mathematica Policy Research will evaluate Virginia's Employment and Training pilot programs designed to increase the number of Supplemental Nutrition Assistance Program (SNAP) participants who obtain unsubsidized employment. Information gained from the evaluation will be used to determine which, if any, of Virginia's three training programs has the greatest impact on increasing employment among SNAP clients.</p> <p><i>Evaluation Methods</i> will include: 1) SNAP client surveys at 12 and 36 months after random assignment to treatment/control group; 2) SNAP client focus groups; 3) employer focus groups; 4) SNAP client case studies, and 5) local DSS staff case studies. Clients will be randomly assigned to intervention or control group within each of the three training options.</p> <p><i>VDSS Role:</i> 1) Provide to Mathematica Policy Research personally identifiable information (administrative data) about clients who agree to participate in the evaluation. 2) DSS local staff will recruit prospective participants, conduct consent discussions, collect registration data, and refer participants to appropriate training programs. Provide space in local DSS offices as required for the study.</p> <p><i>Funding Source(s):</i> United State Department of Agriculture (USDA), Food and Nutrition Service (FNS); Section 16(h)(1)(F) of the Food and Nutrition Act of 2008 (the Act), as amended by the Agricultural Act of 2014 (P.L. 113-79),</p>

Study Title: Impact of Burnout, Compassion Fatigue, and Vicarious Trauma Among Child Protective Services Workers

Study #	2016-07
Principal Investigator (PI)	Donna Harrison and Shannon Rivera
PI Affiliation	Virginia Commonwealth University, School of Social Work
IRB Review Type	Exemption Category 2, survey procedures; 45 CFR 46.101(b)(2)
IRB Decision & Date	Approved; March 15, 2016
Status as of June 30, 2016	Closed
Study Description	<p>A study designed to describe how burnout, compassion fatigue, and vicarious trauma impacts child protective services workers. This study will also examine whether years of experience and number of cases correlates with burnout, compassion fatigue, and vicarious trauma in workers.</p> <p><i>Methods:</i> An internet survey that Child Protective Services workers will complete via Survey Monkey.</p> <p><i>VDSS Role:</i> VDSS Family Services Division CQI Manager, was the project coordinator. Also, the VDSS role included downloading survey results from Survey Monkey and removing all personally identifiable information (PII), including IP addresses. By design, Family Services Division did not retain any record of staff identifiers. If at any time the PI or Family Services Division wants to reuse this information for other purposes or disclose the information to other individuals, the PI/Family Services Division will seek approval from the VDSS IRB.</p> <p><i>Funding Source(s):</i> None; survey was conducted using VDSS access to Survey Monkey and under the supervision of the Division of Family Services.</p>

Study Title: National Food Study Pilot

Study # 2016-08

Principal Investigator (PI) Janice Machado

PI Affiliation Westat

IRB Review Type Expedited, study involves the participation of minors in survey activities; thus, does not qualify for exempt review (45 CFR 46.401(b))

IRB Decision & Date Tabled, August 8, 2016

Study Description The main objective of the National Food Study (NFS) pilot is to test an alternative method of collecting data on the foods acquired by American households that leads to more complete and accurate information about patterns of food acquisition. Other objectives are to explore the feasibility of expanding the population of interest to include households receiving benefits from the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) and to collect more complete and accurate information on income. Data will be collected from households in nine states.

Methods: The survey will collect nationally representative data from 500 households, including 150 households participating in the Supplemental Nutrition Assistance Program (SNAP). Each eligible household will be asked to record food acquisitions for each household member over a 7-day period.

VDSS Role: Release of SNAP administrative data for use in identifying an address-based sampling frame.

Reasons tabled: The requirement to obtain the legally effective informed consent of individuals before involving them in research is one of the central protections provided for under the HHS regulations at 45 CFR 46. The consent and assent process are not consistent with the requirements of 45 CFR 46.116, 45 CFR 46.117(a), 45 CFR 46.117(b)(1). The investigator was notified in writing of the modifications required to secure IRB approval.

Funding Source(s): The U.S. Department of Agriculture, Economic Research Service (ERS) and the Food and Nutrition (FNS) Service; Federal Register Vol. 81, No. 66, Wednesday, April 6, 2016; Pages 19951-19953

Study Title: The Evaluation of Food Insecurity Nutrition Incentives (FINI) Grants

Study #	2016-09
Principal Investigator (PI)	Tracy Vericker, Ph.D.
PI Affiliation	Westat
IRB Review Type	Exempt, 45 CFR 46.101(b)(5)
IRB Decision & Date	Approved, August 9, 2016
Study Description	<p>The purpose of this evaluation is to provide USDA Food and Nutrition Services with an assessment of the implementation experiences and outcomes of nutrition incentive programs targeting SNAP participants that involve a broader range of settings, project features, and participants. The primary outcomes of interest include changes in participants' knowledge and attitudes toward fruits and vegetables, amounts of fruits and vegetables purchased and consumed, household food security, perceived health status, and shopping patterns.</p> <p><i>Methods:</i> SNAP client survey, interviews and analysis of client level administrative data.</p> <p><i>VDSS Role:</i> VDSS will provide client identifiable SNAP administrative data to Westat.</p> <p><i>Funding Source(s):</i> The U.S. Department of Agriculture, The evaluation is being conducted per Section 4208 of the Agricultural Act of 2014 (PL 113-79).</p>

Study Title: Evaluation of Demonstration Projects to End Childhood Hunger (EDECH)

Study #	2016-10
Principal Investigator (PI)	Ronette Briefel, MD
PI Affiliation	Mathematica Policy Research, Inc.
IRB Review Type	<i>No IRB action taken</i>
IRB Decision & Date	Closed. Mathematica decided client level SNAP data was not needed to answer the main study objectives and use of “summer SNAP” data was not essential to the evaluation.
Study Description	<p>The purpose of the demonstration projects is to test innovative strategies to end childhood hunger. The Virginia Department of Education (VDOE) will implement the Virginia Hunger-Free Kids Act Demonstration Project. Project schools will serve three meals a day to all children during the school year and provide food backpacks for weekends and school breaks. In addition, the project will extend an enhanced SNAP benefit or electronic benefits transfer (EBT) card during the summer months to low-income households.</p> <p><i>Methods:</i> The evaluation includes a rigorous impact analysis of each demonstration project as well as implementation and cost-effectiveness analyses. The impact analysis will use a random assignment design to compare food security outcomes between respondents receiving benefits with those not receiving benefits at a 12 month follow up. The evaluation will also examine the demonstration projects' impact on participation in nutrition assistance programs, as well as food shopping and spending.</p> <p><i>VDSS Role:</i> 1) Through a sub-contract with VDOE, VDSS will provide enhanced EBT cards to demonstration project participants and lease SNAP administrative data to the project evaluation team.</p> <p><i>Funding Source(s):</i> The U.S. Department of Agriculture, Food and Nutrition Service; pursuant to the Healthy Hunger-Free Kids Act (HHFKA) of 2010 (P.L. 111-296, Sec. 141)</p>

Continuing Reviews

Any study that continues beyond the initial one-year IRB approval must undergo continuing review⁴. During SFY 2016, the IRB conducted two continuing reviews. Each study is summarized below.

Study Title: Wendy's Wonderful Kids Post-Adoption Study: How are adopted foster youth faring as young adults?

Study #	2014-04
Principal Investigator (PI)	Karen Malm
PI Affiliation	Child Trends
Initial approval	March 26, 2014, Expedited Review
IRB continuing review completed	Two continuing reviews approved; most recent, 3/15/2016.
Status as of June 30, 2016	Study ongoing; As of the most recent approval, two of the 42 eligible adoptees have completed the study. The IRB approved consent form will expire November 2, 2016 and will require continuing review.
Study Summary	<p>A study of outcomes experienced by former foster care youth who were adopted through the Wendy's Wonderful Kids (WWK) program. Participants are young adults who entered foster care at age 8 years or older and who were placed in adoptive homes through the WWK program. Adoptees will be invited to participate as they reach their 19th birthday. The study will assess well-being and any challenges faced in young adulthood, including disruptions occurring during adoption. The PI obtained a Certificate of Confidentiality, dated 1/27/2014, from the National Institutes of Health, US Department of Health and Human Services.</p> <p><i>Methods:</i> A survey will be administered using in-person one-on-one interviews. Interviews will take place either in the participant's home or in a neutral location.</p> <p><i>VDSS Role:</i> Establish initial contact, recruit prospective survey participants and obtain permission for the research staff to contact prospective participants. VDSS staff will use contact information provided by the PI.</p>

4 (45 CFR 46.109(e) and 22VAC40-890-70(F))

Funding Source(s): Dave Thomas Foundation for Adoption

Study Title: Virginia Infant and Toddlers Specialist Network

Study #	SFY 2010-10
Principal Investigator (PI)	Amy Bornhoft
PI Affiliation	Child Development Resources
Initial approval date	July 24, 2009, Exempt Review
IRB continuing review completed	September 24, 2015; this approval has no expiration date and no requirement for continuing review as long as there are no changes to study procedures as approved by the IRB.
Status as of June 30, 2016	Ongoing evaluation
Study Summary	The evaluation is intended to yield output measures and address three main issues: (1) The extent to which the project is successful in implementing planned activities; (2) The extent to which caregivers/teachers/directors and the Infant and Toddler Specialists perceive services as being useful and meeting their needs; and (3) The measurable results or benefits of the services provided by the Infant and Toddler Specialists. Outcomes might include: increased quality of care and education; use of health, safety, and child development knowledge and skills when providing care; and the increased use of resources, services, and linkages with partners.

VDSS Role: contract administration

Funding Source(s): VDSS (Division of Child Care and Early Childhood Development) Contract Number CCD-08-069.

Significant Changes from Research Proposals as Approved by the IRB

Study Title: Project Social Emotional Education & Development (SEED) Evaluation

Study # 2014-06

Principal Investigator (PI) Susan J. Murdock, Ph.D.

PI Affiliation Partnership for People with Disabilities, Virginia Commonwealth University

Initial approval date April 10, 2014

Status Study closed April 9, 2015

IRB Determination On July 24, 2015, the VDSS IRB convened to consider matters related to the SEED Evaluation (See minutes at Appendix B). The IRB found that the PI failed to comply with the terms and conditions of VDSS IRB approval. Specifically, the IRB approval letter, dated April 10, 2014, provided notice that the exploratory study, now known as the *ASQ-3 Screening Project*, required submission of a separate request for IRB review because that aspect of the evaluation involved obtaining identifiable information from VDSS clients.

The PI's failure to obtain VDSS IRB review resulted in an inadequate consent process. Most concerning, the consent process did not inform clients that entitlement to services would not be affected by their decision about ASQ-3 participation. In addition, clients received no information about data confidentiality or the transfer of their identifiable information to a third party.

VDSS Role: contract administration

Funding Source(s): VDSS Contract # CECD-13-003

Corrective Action: The VDSS IRB offered technical assistance to the local department of social services to design a consent process in support of client voluntary ASQ-3 screening.

Results of Closed Studies

In compliance with the legislative mandate⁵, the results of all completed IRB-approved research studies are presented on the IRB Internet web site (<http://www.dss.virginia.gov/about/irb.cgi>) under the heading “Results of Approved Projects.” The three studies listed below were completed and/or the case file was closed during SFY 2016.

Study Title: Impact of Burnout, Compassion Fatigue, and Vicarious Trauma Among Child Protective Services Workers

Study # 2016-07

Principal Investigator (PI) Donna Harrison and Shannon Rivera

PI Affiliation Virginia Commonwealth University

Initial Approval Date March 15, 2016

Closure Date May 2016

Study Purpose: The purpose of this study was to examine if years of experience and number of cases correlates with burnout, compassion fatigue, and vicarious trauma in child protective services (CPS) workers. The researchers hypothesized that CPS workers with a year or less of experience have an increased risk of burnout, compassion fatigue, and vicarious trauma. It was also hypothesized that CPS workers with a high number of cases have an increased risk for burnout, compassion fatigue, and vicarious trauma.

Study Findings: A sample was derived from VDSS staff and surveys were distributed using Survey Monkey. The ProQol measurement tool was used to obtain scores from the workers on the dependent variables- burnout, compassion fatigue, and vicarious trauma. Using independent t-tests, associations were examined between the independent and dependent variables. Results indicated there was no statistical significance between years of experience and number of cases and burnout, compassion fatigue, and vicarious trauma. There was some correlation between a higher number of cases and burnout and vicarious trauma, which supported the hypothesis. The results did not support the hypothesis related to years of experience, but there appeared to be some relationship between higher years of experience and increased scores for burnout, compassion fatigue, and vicarious trauma. Finally, the study outlined points for future research on burnout, compassion fatigue, and vicarious trauma and implications for social work practice.

5 Code of Virginia Section 32.1-162.19

Study Title: Fairfax County Department of Family Services Customer Satisfaction Survey

Study # 2016-02

Principal Investigator (PI) James M. Ellis, PhD

PI Affiliation Center for Survey Research, University of Virginia

Initial Approval Date August 28, 2015

Closure Date January 29, 2016

Study Purpose: The 2015 Fairfax County Department of Family Services (DFS) Customer Satisfaction Survey was conducted during the fall of 2015 by the Center for Survey Research at the University of Virginia. From a list of 3,500 clients, 882 clients completed the survey, yielding a response rate of 27.9% after estimating that 339 clients were ineligible for the survey.

Study findings: Overall, clients are very satisfied with DFS services. The mean rating for overall satisfaction with DFS services is 5.98 on a scale from 1 to 7 where 1 means “Very Dissatisfied” and 7 means “Very Satisfied.” This overall rating of 5.98 is not significantly different from the 6.00 reported in 2013, 5.96 reported in 2011, 5.99 reported in 2009, or 6.07 reported in 2007.

To summarize, the overall performance ratings for DFS services are mostly favorable, with the goal category of “Politeness and Professionalism” being the area of greatest strength. The areas of concern are “Quality of Life” and “Responsiveness to Needs.”

Fairfax County’s Department of Family Services should take pride in its favorable rating for overall satisfaction among clients and for how it has been able to sustain this favorable rating across surveys spanning several years. Raising performance ratings for important goal categories, as well as striving to maintain current strengths, can further improve Fairfax County’s Department of Family Services. Survey ratings for the individual items that comprise these goal areas can help focus attention on areas for further discussion. Ratings for those individual items are detailed in the body of this report.

Study Title: Mind the Gap: An Assessment of Needs in the Hampton Roads Bhutanese Refugee Community

Study #: 2015-02

Principal Investigator (PI): Rena Gautam

PI Affiliation: Christopher Newport University (CNU)

Funding Source Ferguson Foundation and CNU's Center for community Engagement

Initial Approval:

Date September 11, 2014

Closure Date: September 10, 2015

Study Purpose: Recent studies indicate that Bhutanese refugees in particular are experiencing a difficult transition to life in America. To understand the experience of Bhutanese refugee households in the Virginia Peninsula community a teams of student and faculty researchers worked alongside translators to conduct a needs assessment.

Study findings:

Demographics:

- 55 households were surveyed representing 270 Bhutanese refugees.
- The average length of time in the United States: 3.9 years (most have never left this area).
- Average household size: 5 (households range from 2 to 10); most live in 2-bedroom apartments.
- Average age of household members: 28.7.

Education:

Over one-third (36%) have no formal education; the adults in the community have an average of 5.7 years of education.

- Amount of education is significantly related to age; he older the refugee, the less formal education they have received.
- High school students have a difficult time catching up in school and passing standardized tests.
- Parents have difficulty communicating with teachers and school administrators and with helping with their children's homework.
- Upon arrival to the U.S., girls are farther behind than boys.
- Parents do not know how to help their children plan for higher education.

Employment:

- Of the 172 household members between the ages of 18-64, 46% are employed full-time.
- Most are employed at a few key sites, (Smithfield Foods and Canon, for example); many work third shift.
- Many refugees work in excess of 60 hours per week.
- Many are interested in owning their own businesses but do not know how to start.

Study Title: Mind the Gap: An Assessment of Needs in the Hampton Roads Bhutanese Refugee Community

- Gender and age are both significantly related to employment; women and older adults are the least likely to be employed.

Health/Mental Health:

- Three-quarters report they are in poor or fair health.
- 60% report at least one family member has had a recent serious health problem.
- High levels of monthly emergency room visits.
- 20% report a family member with a mental health problem.
- 35% of household members do not have health insurance.
- Half of respondents have significant unpaid medical bills.

Safety:

- Because of the areas in which they live, crime rates are high and safety is a concern.
- At least 10 respondents report having been physically attacked.
- Refugees report being threatened by co-workers and community members.

Language:

- 63.6% of households report no one speaks English very well.
- Overall, women who did not go to a U.S. high school report the lowest levels of English proficiency.
- Lack of English proficiency is linked to difficulties in all other areas, including accessing health/mental health care, communicating with law enforcement (or a potential attacker), communicating with schools, communicating with employers and co-workers, etc.

Conclusion

Half of the 10 initial review studies considered by the IRB during the fiscal year were demonstration projects designed to evaluate aspects of the Supplemental Nutrition Assistance Program (SNAP). Each project is being conducted pursuant to a specific federal statutory authority and the United States Department of Agriculture commissioned and is overseeing an independent evaluation of each demonstration project.

All research reviewed by the IRB satisfied the regulatory definition of minimal risk and involved activities such as surveys, interviews and/or used of program administrative data to include client personally identifiable benefit information.

Appendix A: VDSS IRB Membership

VDSS Institutional Review Board Member Roster

Last Name	First Name	Highest Educational Degree(s)	Institutional Affiliation (Position Title)
Cleary	Hayley	PhD, MPP; Developmental Psychology; Public Policy	Virginia Commonwealth University, Assistant Professor
Disse ³	Mary	BA; Psychology Post-Baccalaureate Certificate in Information Systems	VDSS, Division of Information Systems (Business Analyst)
Hawley	Carolyn	PhD, CRC; Health Related Sciences/Rehabilitation Leadership; Certified Rehabilitation Counselor,	Virginia Commonwealth University, Associate Professor
Huff	Richard	PhD; Public Policy and Administration	Virginia Commonwealth University, Assistant Professor
Jennings	Gail	PhD; Psychology	VDSS, Office of Research and Planning (Statistical Analyst Senior)
Jones-Haskins ³	Erika	MSW; Social Work	Virginia Housing and Development Authority (Community Housing Officer for Homelessness and Non-Profits; formerly with Homeward)
Owens ²	Myra	PhD; Health Related Sciences/Gerontology	VDSS, Office of Research and Planning (Statistical Analyst Senior)
Parente	Em	PhD; Social Work	VDSS, Division of Family Services (Program Manager)
Price ¹	Jeff	PhD; Agricultural and Applied Economics; M.A., Anthropology	VDSS
Temoney	Tamara	PhD; Public Policy and Administration	Hanover County Department of Social Services (Assistant Agency Director)

¹ Director, VDSS Office of Research and Planning; ² IRB Chair and Administrator;

³ Nonscientific member

Appendix B: Minutes of Each IRB Meeting

As required in 22VAC40-890-90 A4, this appendix provides the minutes of each SFY 2016 convened meeting of the IRB. The minutes are presented in date order of each of the four convened meetings.

1. The first meeting was held July 24, 2015 with a focus on an issue of noncompliance (Study # 2014-06).
2. The second meeting was held September 15, 2015 with a focus on the initial review of the study entitled “Assessing the Barriers that Constrain the Adequacy of SNAP Allotments (Study # 2016-03).”
3. The third meeting was held November 23, 2015 with a focus on the initial review of the study entitled “The Evaluation of SNAP Employment and Training Pilots (Study # 2016-06).
4. The fourth meeting was held February 4, 2016 with a focus on review of changes required by the IRB to Study #2016-06.

Date and Time: July 24, 2015; 10:08 AM

Place: VDSS, 801 East Main Street, Richmond, VA, 15th floor, Conference Room # 1503

Members Present: 8 (5 needed for a quorum):

X	Disse, Mary	X	Owens, Myra G., PhD	X	Temoney, Tamara, PhD
X	Jennings, Gail, PhD	X	Parente, Em, PhD, LCSW		
X	Jones-Haskins, Erika, MSW	X	Price, Jeff, PhD		
	Murdock, Susan J., PhD	X	Schneider, Jessica P.		

Ad Hoc: None

Absent: Susan J. Murdock Guests: None

Adjourned: 12:22 PM

Review of Minutes from Previous Meeting(s): None

New Protocols: None

Amendments: None

Continuing Review: None

Potential Noncompliance:

Description: The *ASQ-3 and ASQ-SE Exploratory study* was a component of a Memorandum of Agreement (MOA) between the Virginia Department of Social Services (VDSS) and the Partnership for People with Disabilities (VDSS Contract # CECD-13-003; August 15, 2013 through July 31, 2015). The purpose of the agreement was for VCU to provide training and on-site coaching to childcare providers on the social and emotional development of infants and toddlers. In addition, the MOA required the Partnership to promote the social emotional development of infants and toddlers in childcare through existing agencies and organizations.

The MOA Evaluation was entitled "*Project Social Emotional Education & Development (SEED) Evaluation.*" In the VDSS IRB approval letter dated April 10, 2014, the SEED evaluation was determined exempt from further VDSS IRB review. However, the *ASQ-3 and ASQ-SE Exploratory study* was not included in the exemption. In Fact, the approval letter indicated any data collection from DSS clients would require separate VDSS IRB review. The exploratory study involved Hampton DSS clients completing the ASQ-3 questionnaire and Hampton DSS staff entering ASQ-3 scores along with personally identifiable information (PII) into the ASQ-3 Internet database owned by Brooks Publishing Company. The evaluation goal was to determine how well the process worked. Specifically, determine whether parents would complete and return the questionnaire and whether parents required assistance completing the ASQ-3.

On July 14, 2015, the VDSS contract administrator informed the IRB chair about the implementation of the ASQ study and that the Partnership for People with Disabilities had failed to seek VDSS IRB review. This failure occurred despite repeated e-mail communications from the contract administrator to the Partnership that VDSS IRB review was required.

On July 15, 2015, the VDSS IRB Chair suspended the ASQ exploratory project. On July 17, 2015, the VDSS IRB chair and the contract administrator met with staff from the Partnership for

People with Disabilities responsible for the study. During that meeting, Dr. Murdock stated the study was not research and the Partnership approved the consent form used by the local Department of Social Services. Based on review of consent documents, the first DSS client signed the ASQ-3 consent letter on March 26, 2015. As of July 10, 2015, 53 Hampton DSS clients had consented to participate in the study.

On July 22, 2015 the Partnership for People with Disabilities submitted to the VDSS IRB an application requesting exemption from IRB review citing the following criteria:

The project identified above should be approved as exempt from review by the Institutional Review Board, based on the following exemption criteria (*please check all that apply*):

- It is conducted in an established educational setting(s).
- It involves the use of educational tests, survey/interview procedures, or observation of public behavior.
- It involves the collection or study of existing data, documents, or records that are publicly available or recorded in such a manner that subjects cannot be identified.
- It is conducted by, or subject to approval of, the Commissioner and studies or evaluates public benefit and service programs; procedures for obtaining benefits or services; possible changes in procedures; or possible changes in methods or levels of payment.

Discussion: The chair provided an overview of the potential noncompliance and provided the Board documentation related to the issues. The Board discussed the issues and concluded that that the Partnership failed to comply with the terms and conditions of the April 2014 IRB approval.

The IRB's role is to review studies before study implementation (OHRP Policy & Guidance document *Must investigators obtain IRB approval before involving human subjects in nonexempt research?* The VDSS IRB cannot make a determination about exemption for the following reasons. First, the IRB application was submitted more than five months after involving clients in the project. Second, the Board decided that there was insufficient information to make a determination about whether the project was a *systematic investigation designed to develop or contribute to generalizable knowledge* because that decision would be made solely using information provided by the investigator post study suspension. Third, the project is suspended and no more VDSS clients can be enrolled. Finally, the contract under which the evaluation is being conducted ends July 31, 2015.

The board recommended the following actions:

1. The Partnership must cease collecting and analyzing any data collected.
2. The Partnership must destroy any data in its possession.
3. The Partnership forfeits rights to any future use of client level data collected.
4. VDSS should not reimbursement the Partnership for the ASQ-3 project.
5. The VDSS IRB should contact the Hampton Department of Social Service (DSS) and offer technical assistance to design a consent process for use in future non-research related client screening using the ASQ-3.
6. Hampton DSS should notify clients who participated in the ASQ-3 to provide clarification about the study. Areas to address: 1) we did not tell you everything; 2)

here is what you need to know; 3) you have the option to withdraw your participation in the ASQ-3 project; and 4) you have the right to have any information about you deleted from the database maintained by Brooks Publishing Company and any other database connected with the project. NOTE: at the request of the chair, this potential action was tabled pending conversations with Hampton DSS and Smart Beginnings Virginia Peninsular about their roles in the ASQ-3 project.

Decision(s) and Action(s): The IRB was unanimous in its finding that the Partnership for People with Disabilities failed to comply with the terms and conditions of the original VDSS IRB approval. Specifically, the IRB approval letter, dated April 10, 2014, provided notice that the exploratory study, now known as the ASQ-3 Screening Project, required submission of a separate request for IRB review because that aspect of the evaluation involved collection of personally identifiable information (PII) and ASQ-3 screening data from Hampton DSS clients. The IRB acknowledges the Partnership sub-contracted the ASQ project to Smart Beginnings Virginia Peninsula. Nonetheless, the Partnership remains responsible for evaluation of the study, oversight of the sub-contract and compliance with any IRB approval. The Partnership will be notified in writing about this decision.

The Vote on IRB Actions:

Total Voting = 8; Vote: For = 8, Opposed = 0, Abstained = 0.

There were no controverted issues.

Date and Time: September 15, 2015; 11:08 AM

Place: VDSS, 801 East Main Street, Richmond, VA, WebEx conference

Members Present: 5 (5 needed for a quorum):

X	Disse, Mary		Parente, Em, PhD, LCSW
X	Jennings, Gail, PhD	X	Price, Jeff, PhD
	Jones-Haskins, Erika, MSW		Schneider, Jessica P.
X	Owens, Myra G., PhD	X	Temoney, Tamara, PhD

Ad Hoc: None

Absent: Erika Jones-Haskins; Em Parente

Guests: None

Pre-meeting business: The Chair remained all board members to recuse themselves from deliberation and voting on any study submitted to the IRB in which they have a *potential or perceived* conflict of interest. This includes, but is not limited to: service as a principal investigator, co-principal investigator, sub-investigator: receiving funding from the study; serving in a supervisory or subordinate role with the principal investigator of the study; serving as a mentor/trainee relationship with the principal investigator; a family member of the principal investigator; working relationship for grants awarded by VDSS or a LDSS.

Adjourned: 12:21 PM

Review of Minutes from Previous Meeting(s): 7/24/15 meeting

The board recommended the minutes be accepted with the following revision: Add a period after 4th item under section "The board recommended the following actions:".

A. New Protocols: Assessing the Barriers that Constrain the Adequacy of SNAP Allotments (SNAP Barriers Study); Short Name: The Food and Your Household Study, VDSS IRB # 2016-03

Study Background:

Study Summary: On behalf of the Food and Nutrition Service (FNS), United State Department of Agriculture (USDA), Westat will conduct a study among Supplemental Nutrition Assistance Program (SNAP) participants to identify the major individual, household, and environmental barriers affecting the household's perceived ability to have access to a healthy diet. Information gained from the study will be used to determine how, if at all, these barriers can be accounted for in determining SNAP allotments.

Study Methods will include:

- 1) A mail survey, with telephone follow-ups, that will be sent to approximately 4,800 heads-of-households across 30 states.
- 2) An in-home interview of 120 heads-of-households selected from the pool of individuals who completed the survey.

Role of the Virginia Department of Social Services (VDSS). VDSS will provide personally identifiable data (names, addresses, phone numbers, case file household size,

number of children under the age of 18, latest uninterrupted benefit start date, and monthly amount of SNAP benefit) to Westat for every adult head-of-household receiving SNAP as of July 31, 2015.

B. Discussion:

1. The consent form must be mailed to individuals selected for the in-depth interview at least two weeks prior to Westat's arrival at the home to conduct the interview. This procedure will ensure sufficient opportunity for prospective participants to read the consent form and consider whether or not to participate and will minimize the possibility of undue influence of having the interviewers in the home prior to having an opportunity to review the consent form (45 CFR 46.116, Paragraph 1). The protocol should be amended to include this procedure.
2. Screener for those selected for in-depth interviews.
 - a. All scripts must inform prospective participants that the interview will be conducted in the home and, per protocol, that features of the kitchen and eating spaces of the household will be observed.
 - b. Must add a call back script for calls that go to voicemail and the prospective participant returns your call.
3. Submit a revised consent form for the in depth interview.
 - a. Must specify interview eligibility criteria. Be more specific, is positive or negative "food security" an analytic category for selection of interview participants? See protocol summary Page 2, Paragraph 2).
 - b. Ensure consent form readability is no higher than 6th grade.
 - c. The consent form must inform prospective participants that the interview, as planned, will be conducted in their home. Are there options other than an in-home interview? Can the interview be conducted in a public location?
 - d. The consent form must inform prospective participants, per protocol, that features of the kitchen and eating spaces of the household will be observed.
 - e. Will the \$100 payment be pro-rated, if participant withdraws from the study after the interview is in progress but before it is completed or will full payment be given?
 - f. If the interviewers observe unsafe or illegal activities in the home while conducting the interview, what will the interviewers do with that information?
 - g. The IRB recommends addition of section headers to the consent form, such as:
 - i. Title of Research
 - ii. Sponsor
 - iii. Westat Protocol No
 - iv. Investigator Name and Address
 - v. What is this research study about? (Introduction)
 - vi. What is expected of me? (Procedures)
 - vii. Will the research benefit me? (Benefits)
 - viii. What are my risks? (Risks, Inconveniences, Discomforts)

- ix. Will I get paid (Compensation)
- x. Will I have to pay? (cost of Participation)
- xi. Does pregnancy prevent me from participating? (Pregnancy)
- xii. Who will see my information? (Confidentiality)
- xiii. Research related injury including potential liability related to having interviewers in my home
- xiv. Voluntary participation and withdrawal
- xv. Contacts: concerns or complaints regarding this study and rights as a research subject.

4. Mail Survey.

- a. Consent language included in the cover letter for the mail survey must provide information about the \$5.00 to be enclosed with the survey (45CFR46.109(b)). Language included in your script for refusal conversion can be used: *The enclosed \$5.00 is our gift to you, to thank you in advance for your consideration for doing the survey. You are free to keep that money, even if you do not complete the survey.*
- b. Cover letter should inform prospective participants that acceptance of the \$5 and \$20 will not impact eligibility for social services benefits currently being received (45CFR46.109(b)).

5. Telephone Survey.

- a. Revise the following language: *The survey is voluntary and will take about 30 minutes.* Should read: Participation in the survey is voluntary...
- b. If the participant decides to stop the interview, will the \$20 still be paid?

6. The protocol should be specific about all strata to be sampled and should provide information about the sample size for each stratum (45CFR46.111(a)(3)).

7. The following items were reviewed:

- 1) VDSS IRB form *Request for Review and Clearance of Human Subjects Research*
- 2) E-mail exchanges between VDSS IRB chair and Westat study coordinator (Crystal MacAllum), multiple dates
- 3) Westat IRB initial approval letter dated November 19, 2014 "Expedited Approval of SNAP ALLOTMENTS, Project Number 6292 FWA 00005551"
- 4) Westat IRB APPROVEDAmendmentReviewForm2.3.3.2015
- 5) Data use agreement "AGREEMENT FOR DATA EXCHANGE BETWEEN VIRGINIA DEPARTMENT OF SOCIAL SERVICES AND WESTAT" Signed by VDSS and Westat, but not dated
- 6) Protocol: 6292 SummaryCorrectedVersion3.3.15
- 7) App. A: Mail survey cover letter
- 8) App. B: Questionnaire
- 9) App. C: Automated call 1
- 10) App. D: Fed-Ex cover letter
- 11) App. E: Automated call 2

- 12) App. F: Telephone survey intro and consent
- 13) App. G: Refusal Conversion: Frequently asked questions
- 14) App. H: Answering machine message
- 15) App. I: Thank you note
- 16) App. J: Craig's List Ad
- 17) App. K: Screener for In-depth Interview
- 18) App. L Confirmation email for in-depth interview
- 19) App. M: 1 Week prior reminder email/phone script
- 20) App. N: Day prior reminder script
- 21) App. O: Script for scheduling reserve sample
- 22) App. P: In-depth interview consent form and protocol

- C. Decision(s) and Action(s): Tabled, the IRB needs additional information and requires revisions to study documents, as noted in the discussion section of these minutes, in order to complete the review.
- D. The Vote on IRB Actions:
Total Voting = 5; Vote: For = 5, Opposed = 0, Abstained = 0.
- E. There were no controverted issues.
- F. Amendments: None
- G. Continuing Review: None

Date and Time: November 23, 2015 at 13:40

Place: VDSS, 801 East Main Street Richmond, VA, 15th floor, Conference Room # 1503

Members Present: 7 (5 for quorum):

X	Disse, Mary	Arrived 2:17	Parente, Em, PhD, LCSW
X	Jennings, Gail, PhD	Arrived 2:19	Price, Jeff, PhD
	Jones-Haskins, Erika, MSW	X	Schneider, Jessica P.
X	Owens, Myra G., PhD	X	Temoney, Tamara, PhD

Ad Hoc: None

Absent: Erika Jones-Haskins

Guest(s): Faye Palmer (2:15 – 3:15 PM)

Pre-meeting business: The Chair remained all board members to recuse themselves from deliberation and voting on any study submitted to the IRB in which they have a *potential or perceived* conflict of interest. This includes, but is not limited to: service as a principal investigator, co-principal investigator, sub-investigator: receiving funding from the study; serving in a supervisory or subordinate role with the principal investigator of the study; serving as a mentor/trainee relationship with the principal investigator; a family member of the principal investigator; working relationship for grants awarded by VDSS or a LDSS.

Adjourned Time: 3:35 PM

Review of Minutes from Previous Meeting(s): July 24, 2015 and September 15, 2015 minutes approved.

A. New Protocol: The Evaluation of SNAP Employment and Training Pilots (VDSS IRB #: SFY 2016-06)

1. Consent form/process

- a. The consent form must be specific to the Virginia employment and training projects.
- b. The consent process must allow sufficient time for prospective participants to consider whether or not to participate in the evaluation. The consent form must inform prospective participants they have the option to take the consent form home, prior to signing the document, in order to consider whether or not to participate. Reference 45 CFR 46.116, Paragraph 1 and 45 CFR 46.117(b)(1).
- c. Please add the following paragraph as the opening statement of the consent form. "If any information contained in this consent form is not clear, please ask the study staff to explain any information you do not fully understand. You may take home a copy of this consent form to think about or discuss with family or friends before making your decision."

- d. Please add the following language to the consent form” “If you agree to participate, you will be given a signed copy of this form.” Reference 45 CFR 46.117(a)
- e. The consent process should clearly specify study eligibility criteria.
- f. Consent form title should mirror the project title.
- g. Ensure the consent form language is understandable (45 CFR 46.116, Paragraph 1). In addition to simplifying word choice and sentence structure, use of descriptive section headers may aid comprehension. Appropriate section headers include: Title, VDSS IRB NO, Sponsor, Purpose of the Study, Description of the Study and Your Involvement, Risks and Discomforts, Benefits to You and Others, Compensation, Costs, Alternatives to Participation, Confidentiality, Voluntary Participation and Withdrawal, Questions.
- h. At the end of the consent form, please add a few questions to test comprehension of study information.
- i. In accordance with 45 CFR 46.116(a):
 - i. Please add the statement that the study involves research.
 - ii. Explicitly state duration of subject’s participation. Add a time line showing interactions with participants.
 - iii. The IRB notes that a foreseeable risk of participation is loss of data security leading to a breach of data confidentiality. Please inform prospective participants about this risk and how it will be minimized.
 - iv. Information describing the alternative to participation is muddled and should be revised. Current language: “If you do not want to take part, you will only be able to receive regular services but this will have no effect on your [SNAP] benefits.” Acceptable revision: “If you do not want to take part in this research, you will receive regular SNAP services. Regular services include _____.”
The following statement can be better worded “...no effect on your SNAP benefits.” Acceptable revision: “Your SNAP services will not be affected in any way by your decision to participate or not participate.”
 - v. The VDSS IRB expressed concern about the in-person follow up when a participant cannot be reached by telephone to complete a survey. Having a field locator “show up” at a person’s home without invitation may be perceived as coercion or undue influence. We would like you to consider alternatives such as a mail survey or asking the local SNAP case worker to try contacting the client via telephone. If you elect to have the local SNAP worker call nonresponsive study participants, please submit the telephone script to the IRB for approval. Also, after how many attempts will pursuit end?

- vi. The consent form should include an appropriate example of when the law may require the research team to breach the promise that information will be kept private.
- vii. If a prospective participant has questions, they should be instructed to have all questions answered before agreeing to participate in the study. Reference the check box statement: “By checking this box, I agree that I have read this consent form (or it has been read to me). I understand the information provided and voluntarily agree to participate. If I have questions, I can call the study toll-free number at 1-800-xxx-xxxx.”
- viii. Please list the VDSS IRB as the contact for questions about research participants’ rights. “If you have any general questions about your rights as a participant in this research study, you may contact:

2. Protocol

Institutional Review Board

Virginia Department of Social Services 801 E. Main Street,
15th Floor Richmond, VA 23219-2901

Telephone: 804-726-7076

- a. mail: irb@dss.virginia.gov”The protocol must be specific to Virginia’s employment and training grant project.
- b. Ensure that the role(s) of each Team member (Mathematica Policy Research, MDRC, Kone Consulting, Insight Policy Research, and Decision Information Resources) is fully addressed.
- c. Any request for VDSS client administrative data must be described in the protocol and approved by the VDSS IRB prior to release.
- d. In supplement to the electronic informed consent signature, the VDSS IRB requires that the local DSS maintain a paper or scanned copy of signed consent forms.
- e. Please add to the consent form name and signature lines for the person obtaining the consent.
- f. The protocol indicates that at randomization, participants will provide address information. However, the procedures and data capture methods are not stated. Specify data elements and how local DSS staff will transfer information about participants to the research team (random assignment, SSN, address, etc.).

3. Other Study Documents

- a. Only two follow-up surveys included in application; however, the consent form indicates that there may be 3 telephone surveys. Please clarify.
- b. It is not clear whether prospective participants will receive the gift card if survey questions are skipped. If a participant answers some survey questions then elects not to continue answering survey questions or skips many of the questions, will this be processed as a “complete” survey and the gift card issued?
- c. The Survey reminder postcard mentions that participants will receive a letter explaining how they could receive a prepaid card. That letter must be submitted

for VDSS IRB review and approval.

- d. Focus group consent form should be added to the IRB application.
 - e. Case study consent form should be added to the IRB application.
 - f. The IRB must approve all recruitment materials.
- B. Decision(s) and Action(s): Tabled, the IRB needs additional information and requires revisions to study documents, as noted in the discussion section of these minutes, in order to complete the review.
- C. The Vote on IRB Actions:
Total Voting = 7; Vote: For = 7, Opposed = 0, Abstained = 0.
- D. There were no controverted issued
- E. Amendments: None
- F. Continuing Reviews: None

Date and Time: February 4, 2016 at 13:10

Place: WebEx

Members Present: 5 (needed for a quorum 5):

X	Disse, Mary		Parente, Em, PhD, LCSW
X	Jennings, Gail, PhD	Arrived 13:14	Price, Jeff, PhD
X	Jones-Haskins, Erika, MSW		Schneider, Jessica P.
X	Owens, Myra G., PhD		Temoney, Tamara, PhD

Ad Hoc: None

Absent: Em Parente; Jessica Schneider, Tamara Temoney

Guest(s): None

Pre-meeting business: The Chair remained all board members to recuse themselves from deliberation and voting on any study submitted to the IRB in which they have a *potential or perceived* conflict of interest. This includes, but is not limited to: service as a principal investigator, co-principal investigator, sub-investigator: receiving funding from the study; serving in a supervisory or subordinate role with the principal investigator of the study; serving as a mentor/trainee relationship with the principal investigator; a family member of the principal investigator; working relationship for grants awarded by VDSS or a LDSS.

Adjourned Time: 3:40 PM

Review of Minutes from Previous Meeting(s): November 23, 2015 minutes approved

New Protocols: N/A

A. Review of Tabled Protocol: The Evaluation of SNAP Employment and Training Pilots (VDSS IRB #: 2016-06)

The IRB considered the resubmission based on IRB feedback, dated 11/23/2015. The IRB was unanimous in its vote to approve the study with conditions. Mathematica should address the items listed below and provide revisions to the IRB chair.

Consent form/process

- a. The IRB cannot approve the 60-months follow-up survey until the survey is developed and submitted for review. All references to the 60-month follow-up survey must be deleted from the consent form. The PI should submit a modification request to the IRB when details about the 60-month follow-up

survey are finalized.

- b. Mathematica must remove the OMB Control Number and “Public Burden Statement” from client informed consent document. Reference: “Memorandum for the Heads of Executive Departments and Agencies, and Independent Regulatory Agencies”, dated April 7, 2010; from the OMB Office of Information and Regulatory Affairs. This memorandum provides guidance on the Paperwork Reduction Act (PRA). Page 3 of the Memorandum indicates consents do not count as information under the PRA.
- c. Ensure font size is no less than 12 point. Also, ensure the chosen font type is easily read. Specifically, the font type and size should be consistent with ADA standards for print materials.
- d. There is a conflict between the eligibility age range as stated in the consent form and as stated in the protocol. Ensure these documents are consistent.
- e. The IRB recommends the following language for study inclusion criteria:

About 5,500 Virginia SNAP participants like you will be in the study. If you can answer “yes” to all three of the following questions, you may be able to participate in this study:

- 1. Do you receive SNAP benefits from a Virginia Department of Social Services agency that is participating in the study?
 - 2. Are you required to register for work in order to receive SNAP benefits?
 - 3. Are you between the ages of 18 and 59?
- f. The reading grade level overlap between EleVAte Virginia Online (test between grade levels 3 and 5 in reading) and Job Skills Training Program (test between grade levels 5 and 8 in reading) should be corrected. If the grade level overlap is by design, the consent form must inform clients of the procedure that will be used to assign those who test at the 5th grade level to either the EleVAte Virginia Online or the Job Skills Training Program. Also, fully describe the procedure in the study protocol.
 - g. Change “Once your initial Service Option is decided, a computer will randomly put you in one of two groups.” to read “Once your initial Service Option is decided based on your reading level, a computer will randomly put you in one of two groups.”
 - h. Delete last sentence under “Existing Services Group” “You will not be able to get the EleVAte SNAP E&T Program services for the next three years.” The sentence implies that for the next three years, EleVAte SNAP E&T Program services will only be available through participation in the evaluation. If that is not absolutely true, delete the sentence.
- 1. First bulleted item under Information Collected for the Study; change to read: “This information is required to be part of the study. We will also ask you to give us contact information for someone who will know how to get in touch with you if

- we lose contact with you. You are not required to give us this information.”
- j. Second bulleted item under Information Collected for the Study; change second to last sentence to read: “If we cannot reach you by phone, we would like your permission to follow up with you in-person.”
 - k. Risks and Benefits to You and Others section, change the first sentence to read “If you take part in the study, you have a chance to get one of the new services described above.”
 - l. There appears to be a conflict concerning the time interval for collection of existing data prior to the point at which client consent is given. The consent document states “We will start collecting this information beginning 2 years before today and up to 5 years after today.” However, document *16_Data Elements* states “Monthly data to be collected every three months starting in first month of random assignment, with the first extract containing the past 12 months of data, then three months of data each following quarter.” Ensure consistency in all documents.
 - m. Change to read: “After reviewing this form with staff and taking time to consider whether to participate, please check one of the statements below:”
 - I agree that I have read this form (or it has been read to me). I understand the information provided and I voluntarily agree to participate in the study. I also understand that I may stop participating at any time without losing any social services benefits. If I have questions, I can call the study toll-free number at 1-844-288-5645. I will be given a signed copy of the form.
 - I am indicating that I do NOT agree to be part of this study at this time, but I understand that I may change my mind and agree to take part at a later date. If I decide to participate in the study, I will need to call [PROVIDE A TELEPHONE NUMBER] to schedule an appointment.
 - n. Add the following statements to the signature page of the consent form and ensure clients initial the statement.

Permission to release information about me, if you agree, please initial:

_____ I give permission to the Virginia Department of Social Service (VDSS) to release to the research team information about my SNAP, TANF and Medicaid benefits. I also give my permission for VDSS to release to the research team information about the money I earn from employment. I am aware that VDSS will get this information from the Virginia Employment Commission.

2. Protocol

- a. The protocol must address procedures to be followed when a client is not

progressing well in the training, or is disruptive in the training setting or not getting along well with the trainer.

- b. Add to Page 5, end of paragraph 1 “The DSS will maintain a paper copy of the signed consent form in the client record. The electronic system will print out a copy of the consent form and each participant will sign the paper consent.”

3. Other Study Documents

- a. Please advise us of the necessity for collecting client Social Security Numbers (SSN). We are able to match records using first and last name and date of birth.

B. Decision(s): Approved with conditions as noted above. The IRB was also unanimous in its decision to have the IRB Chair review the resubmission to ensure required changes have been made prior to approval.

C. The Vote on IRB Actions:

Total Voting = 5; Vote: For =5, Opposed = 0, Abstained = 0.

D. There were no controverted issues.

E. Amendments: None

F. Continuing Review: None