COMMONWEALTH of VIRGINIA

DEPARTMENT OF SOCIAL SERVICES

Office of the Commissioner

Margaret Ross Schultze
COMMISSIONER

October 1, 2017

MEMORANDUM

TO: The Honorable Terence R. McAuliffe
Governor of Virginia

Members, Virginia General Assembly

FROM: Margaret Ross Schultze

SUBJECT: Report on Human Research Activities

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 the report, please contact me.

MRS:kc

Attachment

ANNUAL REPORT ON HUMAN RESEARCH
State Fiscal Year 2017

October 2017

A Report of the
Department of Social Services
Commonwealth of Virginia

to the Governor and
General Assembly of Virginia

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Executive Summary

Report Mandate

Section 63.2-218 of the Code of Virginia requires the Virginia Department of Social Services (VDSS) 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. The Code also requires the human research committee to report any significant deviations from the proposals as approved.

Background

The VDSS human research committee, known as the Institutional Review Board (IRB), ensures research will be conducted in compliance with federal (45 CFR 46 et seq.) and state (§32.1-162 and 22VAC40-890 et seq.) statutes. The IRB reviews, approves, and monitors research conducted or authorized by VDSS, local departments of social services, VDSS contractors, and VDSS-licensed facilities.

The VDSS IRB reviews social or behavioral studies or evaluations of client services or benefit programs. Potential harm associated with these types of studies is categorized as minimal risk. Primarily, the IRB deals with issues of privacy, confidentiality, equitable treatment, client informed consent, or to a lesser extent, the potential of psychological harm associated with sensitive questions on surveys.

State Fiscal Year 2017 IRB Oversight Activities

During the fiscal year, ten studies came before the IRB. These studies are summarized in this section.

1. Two annual continuing reviews were approved (SFY 2014-04 & SFY 2016-06). IRBs must periodically review the conduct of research that continues beyond the initial approval period [45 CFR 46.109(e)]. For minimal risk studies, the review must be conducted no less than annually.
2. A resubmitted study (SFY 2016-03) to examine perceived barriers to accessing healthy food in SNAP households and determining adequate SNAP payment allotments was approved. The IRB had previously tabled this study on August 8, 2016. (*Tabled* means the IRB requires additional information and changes to study procedures and/or consent process before the study can be approved.)
3. One initial review application was withdrawn (SFY 2016-08) by the investigator after it was tabled by the IRB. The study, which pilots a new method for collecting information on eating and food acquisition behaviors in SNAP households, was tabled because the investigator did not provide sufficient information to the VDSS IRB and was unwilling to change its consent procedures to be in compliance with federal regulations.
4. The IRB coordinated with Virginia Commonwealth University (VCU) to make arrangements for an IRB reliance agreement, which was signed on 6/2/2017. (*Reliance agreement* is a contract between IRBs from multiple institutions that are involved in the same human subjects research study. The agreement allows these institutions to cede IRB oversight, monitoring, investigator responsibilities and other institutional requirements to one IRB. This provides a reasonable method of joint or cooperative review that reduces duplication of effort

and improves efficiency.) VDSS will defer to the VCU IRB for review of study SFY 2017-01. The study was approved by the VCU IRB on April 17, 2017.

5. The IRB made two exempt research determinations (SFY 2017-02 & SFY 2017-05). This means that the research is not required to comply with the requirement of federal IRB policy (45 CFR 46 et seq.). The study involved assessment of training delivered to child care providers.
6. Another initial review application (SFY 2017-03) was withdrawn by the investigator after the VDSS declined to participate in the study. The investigator submitted a request to do semi-structured interviews with local department of social services' child welfare staff who participate in quality improvement case reviews using a specific process. However, the investigator was informed that the state and local family services staff no longer use that process.
7. Rutgers University approved study number SFY 2017-04 by expedited review. VDSS IRB accepted Rutgers' review and has on file Rutgers University approval documents (Protocol # 17-210M). VDSS IRB independent approval is not required as the study involved release of VDSS non-identifying client data. The VDSS IRB reviewed Rutgers IRB documents and participated in the development of the terms for data sharing (Memorandum of Understanding).
8. On January 23, 2017, study number SFY 2016-06 (*EleVaAte Supplemental Nutrition Assistance Program (SNAP) Employment and Training (E&T) Program)* was suspended. This action was taken because the IRB discovered that informed consent was not being documented using the IRB approved Spanish language consent form as required by HHS regulations (45 CFR 46.117(a)). The investigators completed the required corrective actions and the IRB lifted the suspension on January 31, 2017.
9. The IRB convened once during the fiscal year. The purpose of the meeting was to review changes made to a study (SFY 2016-08) the IRB tabled during the prior fiscal year.
10. At the close of the fiscal year, action was pending for a federally-funded study -- *Evaluation of the Procedural Justice Informed Alternatives to Contempt (PJAC) Demonstration.* Assignment of a VDSS IRB number is pending determination of the role of the VDSS Division of Child Support Enforcement in support of the evaluation.

Study details are provided, in chronological order by study number, beginning on Page 5.

Annual Report on Human Research
October 2017

Report Mandate

Section 63.2-218 of the Code of Virginia requires the Virginia Department of Social Services (VDSS) 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. The Code also requires the human research committee to report any significant deviations from the proposals as approved.

Background

This report documents State Fiscal Year (SFY) 2017 activities of VDSS human research committee, known as the Institutional Review Board (IRB). The IRB is responsible for providing guidance and oversight for the human research protection program and for helping to maintain compliance with applicable laws, regulations, and policies. The VDSS IRB provides oversight of human research activities conducted, authorized, or proposed to be conducted or authorized by the VDSS, local DSS, VDSS contractors, and VDSS-licensed facilities (22VAC40-890-40A).

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 information or data collected from participants. Using established regulatory criteria, the IRB may: 1) determine that a study satisfies criteria for exemption determination, 2) is appropriate for expedited review, or 3) requires full board review. Generally, exemption determination and expedited reviews are conducted by the IRB chair and/or one or two other IRB members. For a full board review, the IRB is convened and the research is reviewed and must be approved by a majority of members present at a meeting composed of a quorum.

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. Mostly, the VDSS IRB reviews studies that are classified as minimal risk. The potential harm associated with a minimal risk study is associated with issues of privacy, confidentiality, equable treatment, client informed consent or to a much lesser extent the potential of psychological harm associated with sensitive survey questions.

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 Protection of Human Subjects regulations at 45 CFR 46 et seq. Compliance, known as a "Federalwide Assurance," is a necessary condition for VDSS to receive federal grants that include human research activities. Among other things, the terms of the assurance requires VDSS to operate an IRB. The current VDSS Federalwide Assurance (#FWA00010976) must be renewed no later than July 22, 2020. The IRB is also registered (# IORG0004422) with HHS. Renewal of the registration should be completed no later than March 11, 2019.

The VDSS Office 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, served as the fiscal year 2017 IRB administrator and chair. She was appointed to these roles July 1, 2015. Cumulatively, she has 16 years' experience serving as IRB chair, IRB member or research regulatory coordinator at Virginia state agencies and at Virginia Commonwealth University.

The IRB is composed of ten voting members (Appendix A). Each member was appointed by the VDSS Commissioner and serves a three-year term. IRB membership complies with state and federal human research regulations. The Director of the Office of Research and Planning serves as an Ex-Officio non-voting member and also serves as the IRB Ombudsman.

IRB Functions

Federal regulations mandate that research involving human participants must be reviewed and approved by an Institutional Review Board (IRB) provided for in its assurance filed with the Office of Human Research Protections and will be subject to continuing review by the IRB. The IRB is responsible for providing guidance and oversight for the human research protection program and for helping to maintain compliance with applicable laws, regulations, and policies. The IRB is responsible for the following oversight functions:

1. Determine what activities constitute human participant research.
2. Review, approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy prior to the commencement of the research.
3. Require that information given to participants as part of informed consent is in accordance with appropriate laws and regulations. The IRB may require that additional information be given to the participants when, in the IRB's judgment, the information would meaningfully add to the protection of the rights and welfare of participants.
4. Require documentation of informed consent or waive documentation in accordance with federal and Commonwealth of Virginia laws and regulations.
5. Notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
6. Unless the study has been classified as "Exempt", conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and have authority to observe or have a third party observe the consent process and the research.
7. Suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional official.

Fiscal Year 2017 IRB Activities

During the fiscal year, the IRB reviewed research studies, participated in continuing education activities, and performed necessary operational activities as described in this section. Ten studies came before the IRB and are summarized in this section. Details are presented, chronologically by study number, beginning on Page 5.

1. Two annual continuing reviews were approved (SFY 2014-04 & SFY 2016-06). IRBs must periodically review the conduct of research that continues beyond the initial approval period [45 CFR 46.109(e)]. For minimal risk studies, the review must be conducted no less than annually. During a continuing review, the IRB:
    a. Determines whether there is any new information that would alter the IRB's previous conclusion about risks to subjects and the reasonableness of those risks relative to anticipated benefits;
    b. Evaluates the adequacy of the informed consent process;
    c. Evaluates investigator and institutional issues; and
    d. Evaluates progress of the study.
2. A resubmitted study (SFY 2016-03) was approved by full board review. During the previous fiscal year (August 8, 2016), the IRB tabled this study. *Tabled* means the IRB requires additional information and changes to study procedures and/or consent process before the study can be approved.
3. One initial review application was withdrawn (SFY 2016-08) by the investigator after it was tabled by the IRB.
4. The IRB coordinated with Virginia Commonwealth University (VCU) to make arrangements for an IRB reliance agreement, which was signed on 6/2/2017. (*Reliance agreement* is a contract between IRBs from multiple institutions that are involved in the same human subjects research study. The agreement allows these institutions to cede IRB oversight, monitoring, investigator responsibilities and other institutional requirements to one IRB. This provides a reasonable method of joint or cooperative review that reduces duplication of effort and improves efficiency.)[1] VDSS will defer to the VCU IRB for review of study SFY 2017-01. On April 17, 2017, the VCU IRB approved the study by expedited review.
5. The IRB made two exempt research determinations (SFY 2017-02 & SFY 2017-05). This means that the research is not required to comply with the requirement of federal IRB policy (45 CFR 46 et seq.). The study involved assessment of training delivered to child care providers.
6. Another initial review application (SFY 2017-03) was withdrawn by the investigator after VDSS declined to participate in the study.
7. Rutgers University approved study number SFY 2017-04 by expedited review. VDSS IRB accepted Rutgers' review and has on file the Rutgers University approval documents (Protocol # 17-210M). VDSS IRB independent approval is not required as the study involved release of VDSS non-identifying client data and the investigators will not have access to any client identifiable information. The VDSS IRB reviewed IRB documents provided by the Rutgers PI and participated in the development of the terms for data sharing (Memorandum of Understanding).

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1 For more information about reliance agreements, refer to the VDSS IRB policy document on our public web site (http://www.dss.virginia.gov/files/about/irb/procedures_sections/irb_operations/Reliance_Agreements.pdf).

8. On January 23, 2017, study number SFY 2016-06 was suspended. This action was taken because the IRB discovered that informed consent was not being documented using the IRB approved Spanish language consent form. HHS regulations state: "informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative (45 CFR 46.117(a))." The investigators completed the required corrective actions and the IRB lifted the suspension on January 31, 2017. Study title: *EleVaAte Supplemental Nutrition Assistance Program (SNAP) Employment and Training (E&T) Program*.
9. The IRB convened once during the fiscal year. The purpose of the meeting was to review changes made to a study (SFY 2016-08) tabled during the prior fiscal year.
10. At the close of the fiscal year, action was pending for one federally-funded study -- *Evaluation of the Procedural Justice Informed Alternatives to Contempt (PJAC) Demonstration.* Assignment of a VDSS IRB number is pending determination of the role of the VDSS Division of Child Support Enforcement in support of the evaluation.
11. The IRB provided recommendations for language that should be included in data sharing agreements that involve human research activities.
12. Annual IRB awareness information was released via SPARK broadcast (#10387; April 6, 2017).
13. The IRB developed 12 guidance documents covering IRB operations, informed consent process, and participation of children in research.
14. Maintained a database for tracking the status of IRB reviews, study modifications, and continuations.
15. 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.
16. Three IRB members attended the *Tenth Annual Virginia IRB Consortium Conference*. The daylong conference was held September 30, 2016 at the University of Virginia. The theme was *All Aboard: Single IRB Review and Other Proposed Rule Changes*.

Fiscal Year 2017 Study Details

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)	Maeve Gearing, Ph.D.
PI Affiliation	Westat
Funding Source(s)	Food and Nutrition Service, United State Department of Agriculture (USDA Contract # AG-3198-D-14-0071)
IRB Review Type	Full Board
IRB Decision & Date	1. On September 15, 2015, the VDSS IRB tabled the study. 2. October 2015, the USDA put the study on hold. 3. USDA removed the study from hold. PI revised the study to satisfy the conditions that prompted the IRB to table the study. PI resubmitted the revised study to the VDSS IRB on March 7, 2017. 4. On March 23, 2017, the VDSS IRB approved the study with conditions. 5. Conditions were satisfied and the IRB approved the study on April 24, 2017.
Status as of June 30, 2016	Approved, not yet implemented
Study Description	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 USDA 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 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. *VDSS Role*: 1. Per Data Use Agreement (under review), provide a dataset to Westat via Westat's secure FTP site with a dummy ID for every adult head-of-household receiving SNAP as of October 31, 2017 **No personally identifiable information (PII) will be included in this dataset.** 2. Westat will use the dataset to select a stratified sample (household size, children in household and time on SNAP). Westat will then provide VDSS with the list of dummy IDs for the selected sample. 3. VDSS will use the returned dummy IDs to provide Westat a dataset with the dummy ID and contact information for each

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

	case: Name of head of household, mailing and street addresses, and all phone numbers in the file. Including oversampling, the number of cases is not expected to exceed 320.

Study Title: National Food Study Pilot

Study #	2016-08
Principal Investigator (PI)	Janice Machado
PI Affiliation	Westat
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
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	Withdrawn August 8, 2016
Reason Withdrawn	Westat declined to revise the study so that it complies with regulatory requirements. Westat's proposed consent and assent processes are not consist with the requirements of 45 CFR 46.116, 45 CFR 46.117(a), 45 CFR 46.117(b)(1).
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.

Study Title: Vision 21 Linking Systems of Care for Children and Youth Demonstration Project

Study #	2017-01
Principal Investigator	Jared Keeley, PhD
PI Affiliation	Virginia Commonwealth University
Funding Source(s)	U.S. Department of Justice, Office for Victims of Crime
IRB Review Type	Expedited
IRB Decision & Date	On April 17, 2017, the study was approved by the VCU IRB. On 6/1/2017, VDSS entered into an IRB reliance agreement with VDSS deferring to VCU for study review and ongoing monitoring.
Study Description	Currently, there is no existing screening tool to assess victimization across systems in Virginia. For this reason, the Vision 21 project staff developed the Virginia Victimization Screen (VVS), a brief screening tool to assess: 1) common forms of victimization, 2) behaviors, feelings and symptoms experienced by those who have experienced crime and/or trauma, and 3) protective factors which may assist children and youth in being resilient to adverse experiences. The goal is to learn more about the value and usefulness of a questionnaire. The questionnaire will be piloted to test reliability and validity. In addition, feedback from child-serving professionals will help Vision 21 staff understand the usability of the questionnaire. Approximately five child service provider organizations will participate in the pilot. *Methods:* Interview children under the age of 18 and young adults ages 18-21. Children and their caregivers will be recruited to the pilot at points of service (Ready Kids; Shelter for Help in Emergency; Foothills Children Advocate Center; Albemarle County Department of Social Services; Abuse Alternatives, Inc.; & Court Service Unit). *VDSS Roles:* As the primary awardee of the Vision 21 grant, VDSS is engaged in human subjects research (per OHRP guidance document). Also, two local departments of Social Services will be engaged in conducting consent discussions and administering interviews (screening tool). *Special Note*: No LDSS foster care children/youth can participate in the tool validation process because the LDSS cannot both serve as legally authorized representative to foster care youth and provide permission for those same youth to participate in the Vision 21 screening tool validation process. To do so would be a conflict of interest. This information was communicated to VDSS research staff and VCU in an October 7, 2016 e-mail from the VDSS IRB chair.

Study Title: Child Care Providers and Social Emotional Development Training

Study #	2017-02
Principal Investigator (PI)	Susan Murdock, Ph.D.
PI Affiliation	Virginia Commonwealth University
Funding Source(s)	VDSS
IRB Review Type	Exemption Determination
IRB Decision & Date	Approved September 12, 2016
Study Description	The study involves telephone interviews with approximately four to eight child care providers who participated in at least one of two training activities and completed the pre/post training assessment surveys. Training activities were designed to introduce child care providers to evidence-based practices related to social emotional development of children ages birth to age 5. The two training activities were: 1) Teaching Pyramid Model known as "Center in the Social and Emotional Foundations for Early Learning" (CSEFEL) and 2) Use of a screening tool to detect developmental delays in children known as "Ages and States Questionnaire" (ASQ). Trainings were provided throughout the Commonwealth of Virginia. *Methods:* Open-ended telephone interviews conducted 2 to 3 months post training. *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 data collection.

Study Title: Qualitative Service Review as a Learning Strategy for Child Welfare Practice Improvement

Study #	2017-03
Principal Investigator (PI)	Bethany Womack, MSSW
PI Affiliation	The University of Alabama, Tuscaloosa
Funding Source(s)	Self-funded Dissertation
IRB Review Type	N/A
IRB Decision & Date	Withdrawn
Reason Withdrawn	Qualitative Service Review (QSR) process not used at VDSS; instead, VDSS uses Child & Family Services Reviews (CFSRs) process.
Study Description	The Quality Service Review (QSR) The QSR protocol and review processes use an in-depth case review method and practice appraisal process to find out how well children and their families are benefiting from services received and how well locally coordinated services are working for these children and families. The inquiry process is supported by a case review protocol that measures the performance of core practice functions (in the agency's practice model) in actual cases selected for an in-depth review. The QSR process relates present case practice and results to local conditions and to the goodness-of-fit between the practice model used and the needs of the children and families who present for services. The QSR inquiry process focuses on functional practice performance rather than simple compliance with policies, procedures, and funding requirements. The purpose of the study is to learn about the experience of child welfare direct practice staff in using the QSR. Specifically, assess the effective use of QSR relative to the agency's practice model. *Methods:* Semi-structured interviews (N =12) with child welfare direct practice staff. *VDSS Role:* Provide PI a listing of child welfare staff and E-mail addresses. No clients or client data involved in this proposed study.

Study Title: Virginia Children's Services Practice Model Implementation Study

Study #	2017-04
Principal Investigator (PI)	Kerrie Ocasio, Ph.D., MSW
PI Affiliation	Rutgers, The State University of New Jersey
Funding Source(s)	Casey Family Programs
IRB Review Type	Expedited
IRB Decision & Date	MOU signed on 6/28/2017
Study Description	VDSS and Casey Family Programs (CFP) are engaged in a multi-year project that began in 2014 to strengthen the full spectrum of child welfare services. CFP also entered into an agreement with Rutgers, The State University of New Jersey to evaluate implementation and outcomes of the project. Twenty-two LDSS have agreed to participate in the study. Rutgers will enter into an agreement with VDSS to obtain client administrative data in order to conduct the evaluation. They require: Coded client administrative data, anonymous client surveys, anonymous LDSS staff surveys, and LDSS staff focus group/interview data. Identifiable VDSS employee data includes: agency name, employee name and position title. No client identifiable data will be released as part of this agreement. VDSS will replace client identifiers with a random number and will maintain a crosswalk between client identifiers and the assigned random number. VDSS must ensure that the investigators cannot readily ascertain client identity. VDSS and the investigator(s) agree that the crosswalk shall not be released to the investigator(s). *Methods:* Analysis of administrative data, client and staff surveys, staff interviews and focus groups. *VDSS Role:* Provide coded administrative data, provide access to LDSS and VDSS child welfare staff; ensure all disclosures, exchanges and release of data, records, and information complies with all relevant federal and state laws and regulations. Including federal and Commonwealth of Virginia laws and regulations governing human research protections: 1) Title 45 CFR 46, Subparts A, B, C, and D); 2) Code of Virginia 32.1, Chapter 5.1 Human Research; and 3) Virginia Administrative Code Title 22. Social Services, 22VAC40-890 et seq.

Study Title: Substance Exposed Infants Virginia Policies and Practices Survey

Study #	2017-05
Principal Investigator (PI)	Carrie Redden, M.P.H., M.C.R.P.
PI Affiliation	ToXcel
Funding Source(s)	Virginia Department of Social Services, Contract No. FAM-17-049; *Facilitation of work group regarding Substance Exposed Infants in Virginia*
IRB Review Type	Exemption Determination
IRB Decision & Date	Approved May 31, 2017
Study Description	The purpose of the survey is to gather information about how policies related to substance exposed infants (SEI) are being put into practice across the Commonwealth. In addition, the survey seeks to identify barriers associated with providing services and supports to substance exposed infants and their caregivers. *Methods:* A self-administered anonymous web-based (Qualtrics) survey to be completed by a snowball sample. The survey will be sent to the *VDSS SEI Work Group* and the Virginia *Department of Behavioral Health & Developmental Services Handle with C.A.R.E. Work Group*. Work group participants will be asked to share the survey with others. No E-mail or IP addresses will be collected as part of the survey. *VDSS Role:* Funder and study coordination. The survey is part of a broader study being conducted in response to HB2162 (2017 Session of the Virginia General Assembly) "*Substance-exposed infants; study of barriers to treatment in Commonwealth*" There is no specific intent to involve VDSS clients in data collection.

Continuing Reviews

Any study that continues beyond the initial one-year IRB approval must undergo continuing review[2]. During Fiscal Year 2017, 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	Karen Malm
PI Affiliation	Child Trends
Funding Source	Dave Thomas Foundation for Adoption
Initial approval	March 26, 2014, Expedited Review
Continuing review	Third continuing review approved October 18, 2016
Status	Study ongoing; as of the most recent approval, two of the 42 eligible Virginia adoptees have completed the study and none of the eligible youth have refused to participate.
Study Summary	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. *Methods*: 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. *VDSS Role:* 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.

2 (45 CFR 46.109(e) and 22VAC40-890-70(F))

Study Title: The Evaluation of SNAP Employment and Training Pilots

Study #	2016-06
Principal Investigator (PI)	Michael Ponza
PI Affiliation	Mathematica Policy Research
Funding Source(s)	United State Department of Agriculture (USDA), Food and Nutrition Service (FNS)
Continuing Review Approval	January 31, 2017
Status as of June 30, 2017	Ongoing
Study Description	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. *Evaluation Methods* 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. *VDSS Role*: 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.

Modifications to Approved Studies

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
Funding Source:	VDSS
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, 2017	First phase of pilot completed April 29, 2016. Second phase of pilot completed March 31, 2017. Implementation with Spanish-speaking only participants started 4/3/2017 but was suspended on 6/28/2017 due to an insufficient number of Spanish-speaking participants who were willing to complete the survey.
Study Description	The primary purpose of this anonymous 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 adult family members and friends associated with child clients of local departments of social services who participate in FPMs. Five local departments participated in the first phase of the pilot study. Eight additional local departments plus two from the first phase participated in the second phase of the pilot study. This modification added a Spanish version of the survey and provides procedures to support inclusion of clients who speak Spanish.

Significant Change from a Research Proposal as Approved by the IRB

Study Title: The Evaluation of SNAP Employment and Training Pilots

Study #	2016-06
Principal Investigator (PI)	Michael Ponza
PI Affiliation	Mathematica Policy Research
Funding Source	United State Department of Agriculture (USDA), Food and Nutrition Service (FNS)
Initial approval	February 11, 2016
Status as of June 30, 2016	Ongoing
Study Description	Evaluation of Virginia's Employment and Training pilot programs designed to increase the number of Supplemental Nutrition Assistance Program (SNAP) participants obtaining unsubsidized employment. Study participants are randomly assigned to intervention or control group within each of the three training options.
Reason for Suspension	On January 23, 2017, the VDSS IRB suspended enrollment in the study; specifically, enrollment of participants who require Spanish language consent. This action was taken because the IRB discovered that informed consent was not being obtained and documented using the IRB approved Spanish language consent form as required by HHS regulations at 45 CFR 46.117(a). In addition, affixed to the unapproved consent form was the VDSS IRB approval stamp. However, the approval stamp was not placed on that form by the VDSS IRB. The suspension was lifted on January 31, 2017 after the PI satisfied conditions required before the suspension could be lifted. 1. Study participant records were reviewed to determine whether the unapproved Spanish language consent form had been used. The review indicated none of the study participants required Spanish language consent. 2. The PI was required to certify to the IRB that the electronic consent system now contains the VDSS IRB approved Spanish language consent form.

Results of Closed Studies

In compliance with a legislative mandate[3], 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." There are no closed study results to report this fiscal year.

Conclusion

All research reviewed by the IRB satisfied the regulatory definition of minimal risk and involved activities such as surveys, interviews, professional development training, job training interventions, or use of administrative data. Ten studies came before the IRB during the fiscal year. Two of the ten were withdrawn by their respective investigations. Two exempt research determinations were approved; two studies were approved by expedited review; one study was approved by the VCU IRB, and one study was approved by Rutgers University. Two studies were continuing reviews; of those, one was temporarily suspended to ensure that an IRB approved consent form was being used. The suspension was lifted on January 31, 2017.

At the close of the fiscal year, action was pending receipt of a request for initial review for one study -- *Evaluation of the Procedural Justice Informed Alternatives to Contempt (PJAC) Demonstration* -- involving a direct federal grant to VDSS. Assignment of a VDSS IRB number is pending determination of the role of the VDSS Division of Child Support Enforcement in support of the national evaluation of PJAC demonstration grants.

[3] Code of Virginia Section 32.1-162.19

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[2]	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 (Research Associate Senior)
Jones-Haskins[2]	Erika	MSW; Social Work	Department of Behavioral Health & Developmental Services (Community Support Services)
Owens[1]	Myra	PhD; Health Related Sciences/Gerontology	VDSS, Office of Research and Planning (Research Associate Senior)
Parente[2]	Em	PhD; Social Work	VDSS, Division of Family Services (Program Manager)
Schneider	Jessica	MS; Criminal Justice	Virginia Department of Juvenile Justice
Temoney[2]	Tamara	PhD; Public Policy and Administration	Hanover County Department of Social Services (Assistant Agency Director)
Price[3]	Jeff	PhD; Economics	VDSS Office of Research and Planning (Director)

[1]IRB Chair and Administrator; [2]Nonscientific member; [3]Ex-Officio non-voting member & IRB Ombudsman

Appendix B: Minutes of Each IRB Meeting

A copy of the minutes of each Fiscal year 2017 convened meeting of the IRB is presented in this appendix (22VAC40-890-90A4). The IRB convened once (March 23, 2017) during the fiscal year to consider revisions to a study (2016-03) that the IRB Tabled during the previous fiscal year.

Study number 2016-03 was *approved with conditions* at the March 23, 2017 meeting. After the investigators took appropriate corrective actions, the study was approved on April 24, 2017.

The IRB found that the research presents no more than minimal risk of harm to prospective participants and involves no procedures for which written consent is normally required outside of the research context. Therefore, the IRB waived the requirement to document informed consent for the mail survey, including telephone follow-up.

Date: 3/23/17
Place: VDSS, 801 East Main Street Richmond, VA, 15th floor, Room # 1518

Call to order Time: 15:04
Members Present: 10 members, six for a majority: Seven present for today's meeting

IRB Member Attendance Table

Present	Scientist (S) Non-scientist (N)	IRB Member	In person (I); WebEx; Telephone (TP)	Arrival Time	Departure Time (s)
☒	S	Cleary, Hayley, PhD, MPP	WebEx	15:01	16:23
☐	N	Disse, Mary, B.A.			
☒	S	Hawley, Carolyn, PhD, CRC	I	14:56	16:23
☐	S	Huff, Richard, PhD			
☒	S	Jennings, Gail, PhD	I	14:56	16:23
☒	N	Jones-Haskins, Erika, MSW	WebEx	15:00	16:23
☒	S	Owens, Myra G., PhD	I	14:45	16:23
☐	N	Parente, Em, PhD, LCSW			
☒	S	Schneider, Jessica P.	WebEx	14:47	16:23
☒	N	Temoney, Tamara, PhD	WebEx	15:00	16:23

Voting Members Absent: Mary Disse, Richard Huff, and Em Parente

Attendance Table – all others present at any time during the meeting:

Name	Time arrived	Time departed	role during the meeting
None			

The Chair introduced board members Drs. Cleary and Hawley; then all board members introduced themselves.

The Chair reminded 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.

Review of Minutes from Previous Meeting(s):

Meeting Date	Accept as is	Accept with Revisions*	Revise & Resubmit*	*see minutes for revision
N/A	☐	☐	☐	☐

There were no new protocols, amendments or continuing reviews. Tabled study SFY 2016-03 was the sole matter for board consideration. Dr. Owens provided a summary of the study and prior VDSS IRB actions.

On behalf of the USDA, 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 to determine how, if at all, these barriers can be accounted for in determining SNAP allotments. Research activities include: 1) Mail survey, with telephone follow-ups approximately 160 VDSS SNAP heads of households. 2) In-home interview approximately 5 VDSS SNAP heads of households who completed the survey. Westat requests that VDSS provide personally identifiable information (PII) on all SNAP clients; Westat plans to use the PII to select the Virginia sampling frame.

Dr. Owens noted that under federal IRB regulations, providing PII does not constitute engagement in human subjects research. However, a number of deficiencies were noted concerning the Westat client informed consent process; thus, prompting VDSS IRB review. Also, 22VAC40-910-50 provides authority for VDSS IRB review of this study.

A. **Tabled Study** (September 15, 2015) – **revised and re-submitted** (March 6, 2017):

Study Title: 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	Sponsor/Funder: USDA, Food and Nutrition Service
Investigator: Maeve Gearing, Ph.D.	Primary reviewer(s): Myra G. Owens, Ph.D.
Action Items:	N/A
Discussion and Questions:	1. There was discussion concerning the study risk level. Some members expressed concern about the in-home interview as infringement on home as an intimate and private space. The definition of minimal risk was reviewed and all members agreed that the study satisfies the federal definition of minimal risk [45 CFR 46.102(i)]. 2. There was discussion about Westat's itemized response to Tabled study issues. There was unanimous agreement that issues were adequately addressed. The exception is as follows: Add section header "WILL THE RESEARCH BENEFIT ME?" and

provide appropriate information for this heading. Rationale – Prospective research subjects are economically vulnerable. IRBs have authority to require additional safeguards to protect the rights of vulnerable prospective research participants [45 CFR 46.111(b)]. In deciding whether to take part in the study, prospective research participants have a right to know that there will be no direct benefit.

3. Dr. Owens noted that she had conversations with benefits program managers to ascertain whether incentive payments would adversely affect eligibility for DSS benefits programs. Confirmation received that payments would not impact program eligibility.

4. Dr. Owens noted that the Westat data request requires VDSS to violate the confidentiality of all active SNAP heads of household in the interest of a very small Virginia sample. However, per study protocol, eligible respondents include heads of households with an address or phone number on the file. The IRB recommends that VDSS draw the sample using Westat criteria or that VDSS provide encrypted data for sampling purposes and then only release the sample selection.

5. Interview Consent form:
    a. "WHAT IS THIS RESEARCH STUDY ABOUT?" section; add to the first paragraph the following: "The purpose of this consent form is to help you decide if you want to be in this research study. You should not join this research study until all of your questions are answered."
    b. Typo correction "WHAT ARE MY RISKS" section; If any questions ~~that~~ make you uncomfortable, you can tell us to skip them.
    c. "WHAT ARE MY RISKS?" section; add: "If the interviewer observes someone in danger, she or he will report it to the appropriate authorities. If the interviewer observes activities that are illegal, but that pose no danger to the respondent or others, no action will be taken."
    d. Add section header "WILL THE RESEARCH BENEFIT ME?" and provide appropriate information for this section. Rationale - Prospective research subjects are economically vulnerable. IRBs have authority to require additional safeguards to protect the rights of vulnerable prospective research participants [45 CFR 46.111(b)]. In deciding whether to take part in the study, prospective research participants have a right to know whether they will directly benefit from the research.
    e. "WHO WILL SEE MY INFORMATION?" section; describe "hurting someone". It is physical hurting or is it more comprehensive?
    f. "VOLUNTARY PARTICIPATION AND WITHDRAWAL"

section, change to read ~~Your participation in this interview is voluntary. There is no penalty if you decide not to participate. It will not have any effect on your SNAP benefits or any other benefits you get.~~ It is your decision whether or not to participate in the interview. Your social services and benefits will not change based on what you decide about the study. ~~You may end the interview at any time.~~ You may skip questions that make you uncomfortable. You may end the interview at any time. There is no penalty.

g. Replace the check boxes on the signature page of the consent form with space for initials

☐ I agree to participate in the interview.

☐ I agree to have my interview audio-recorded.

6. Survey consent:

Your decision to participate will not affect your benefits in any way, either now or in the future may skip any question that you do not want to answer or stop the interview at any tim we would really appreciate your answering all the questions you can.. Your answers w kept private and the results of the survey will be reported as totals so that no one perso be identified. Do you agree to participate?

a. Change to read: It is your decision whether or not to participate in the survey. Your social services and benefits will not change based on what you decide about the study. You may skip questions that make you uncomfortable. You can stop the interview at any time. There is no penalty." Your answers will be kept private and the results of the survey will be reported as totals so that no one person can be identified. Do you agree to participate?
b. Appendix F.1 TELEPHONE SURVEY INTRODUCTION AND CONSENT – 2-24-17. The telephone script for the mail survey assumes the prospective participant read the "PARTICIPANT SURVEY INTRODUCTORY LETTER". This is not a good assumption. The telephone survey introduction should address all the same information as the mail survey introductory letter. For example: what this study is about, type of questions to expect, you can keep the $5, etc…
c. PARTICIPANT SURVEY INTRODUCTORY LETTER should inform prospective participants how much of their time is required to complete the survey.

7. Study Protocol (6292 Summary):
   a. Clarify whether the "raw data" to be delivered to FNS includes the audio files. If audio files will be provided to FNS, consent form should inform prospective participants. Enumerate items that are "raw data".

	b. Provide rationale for the need and use of "Craig's List" advertisement. What circumstances will prompt the use of the ad? c. Westat should promptly inform the VDSS IRB about the nature of each contact from a VDSS study participant who has a concern about the study.
Controverted issues:	There were no unresolved controverted issues.

Decision:	Approve ☐	Approve with Conditions ☒	Table ☐	Disapprove ☐
Vote:	Total Voting = 7	Vote: For = 7	Opposed = 0	Abstained = 0

Approval period:	One Year

The research presents no more than minimal risk of harm to prospective participants and involves no procedures for which written consent is normally required outside of the research context. Therefore, the IRB waived the requirement to document informed consent for the mail survey with telephone follow-up.

The IRB designated the chairperson to review subsequent responses from the investigator to determine whether conditions identified at this meeting have been satisfied. No further review for this study at a convened IRB meeting is necessary.

Number of voting members not in the room = 0	Number of voting members not present due to conflict of interest = 0	

Adjourned Time: 16:23