COMMONWEALTH of VIRGINIA

DEPARTMENT OF SOCIAL SERVICES

Office of the Commissioner

S. Duke Storen
COMMISSIONER

October 1, 2019

MEMORANDUM

TO: The Honorable Ralph S. Northam
Governor of Virginia

Members, Virginia General Assembly

FROM: S. Duke Storen

SUBJECT: Report on Human Research Activities

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

SDS:kc
Atttachment

ANNUAL REPORT ON HUMAN RESEARCH
State Fiscal Year 2019

October 2019

A Report of the
Department of Social Services
Commonwealth of Virginia

To the Governor and
General Assembly of Virginia

Table of Contents

Contents

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 as well as any studies that utilize or seek to gather information about VDSS and/or LDSS clients and/or employees.

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 and, to a lesser extent, the potential of psychological harm associated with sensitive questions on surveys. To meet the responsibilities of federal and state statutes defined above, the VDSS is guided by practices provided by the Office of Human Research Protections, in the U.S. Department of Health and Human Services (USDHHS) at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/index.html.

ACTIVITIES OF THE VDSS IRB IN SFY 2019

Board Meetings

The IRB convened twice during the fiscal year, once on February 21, 2019 and again on April 9, 2019. At the meeting February 21st, the IRB conducted a full board review of IRB #2019-05 from Total Child Health (CHADIS), Baltimore MD. The Board had numerous questions about the study, and these issues were communicated to the PI submitting the research (Kerry Ann Bet MPH, CHES, Research Coordinator). The PI responded to these questions May 31, 2019, and the Board will review the proposed research again at the next meeting planned for September 2019. Questions and discussion by about this proposed research are included in minutes of the February 21st meeting found in Attachment C.

At the meeting April 9th, no studies required full board review however, the board reviewed studies approved to date, both exempt and expedited. Key topics of discussion for the board at this meeting included: final revisions to the Common Rule, specifically those related to concepts of Broad Consent and Limited Review; use of Reliance or Authorization Agreement; application of VDSS IRB Criteria for Review to studies before engaging the Board in a review of submission research. More detail of these discussion are provided in the minutes of the April 9th meeting found in Attachment C.

During SFY 2019, twenty-two (22) research studies came before the IRB. The IRB's actions are summarized below.

Studies Approved as Exempt from IRB Review

The IRB determined eight (8) studies to be Exempt from Review. Federal (45 CFR 46 et seq.) and state (§32.1-162 and 22VAC40-890 et seq.) statutes describe several categories of research that do not require IRB review. However, the IRB determines if a research study meets the requirements for Exempt status. Studies submitted to the VDSS most often fall into two categories of exemption as defined in the statutes. The first category describes research using information about human subjects that is never linked (directly or indirectly) to any individual through personal identifiers. Furthermore, disclosure of the subject's information outside the research would not reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation. The second category describes research and demonstration projects that are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine public benefit or service programs.

Studies Approved under Expedited Review Procedures

The IRB approved eleven (11) studies through Expedited Review Procedures. A study qualifies for expedited review if research activities (a) present no more than minimal risk to human subjects, and (b) involve only secondary analysis of existing data, documents, or records originally collected for non-research purposes. The VDSS IRB Chair and one other IRB member conduct expedited reviews. Of the eleven studies approved under Expedited Review, six (6) submissions consisted of Modifications to initially approved research and two were continuing reviews required by the initial IRB approval. Three studies were approved for Initial Expedited Review however, one study was later withdrawn. The two remaining studies approved in SFY2019 are in progress and have strong VDSS agency sponsorship.

Studies Approved through Reliance/Authorization Agreement

The IRB approved three (3) studies by Reliance Agreement, also referred to as an Authorization Agreement. A reliance agreement is a contract between IRBs from different institutions involved in the same human research study, whereby one institution agrees to cede IRB oversight and monitoring to the other IRB. This provides a reasonable method of joint or cooperative review that reduces duplication of effort and improves efficiency. All Reliance Agreements entered into by VDSS are reviewed in detail by the VDSS IRB chair and approved by the VDSS Commissioner. Criteria for Reliance Agreements, as discussed by the VDSS IRB at their April 2019 meeting include: known and reputable research organization or university; clear and engaged PI and institutional individuals accessible to respond to VDSS IRB questions when needed; thorough review of all study materials of the initial submission to the relying institution by the VDSS IRB Chair. Reliance Agreements undertaken by VDSS in SFY2019 were with the following entities:

- ICF, PI Christine Leicht and VDSS PI Carl Ayers. *Prenatal Alcohol and Other Drug Exposures in Child Welfare (PAODE_CW)* sponsored by the US DHHHS, Children's Bureau.

- Urban Institute, PI Kristin Blagg, and VDSS PI Jeff Price. *How do students us social safety net supports before, during, and after college enrollment?* Sponsored by the Virginia Division of Benefit Programs and Office of Research and Planning.
- University of Richmond, PI Lisa Jobe-Sheilds and VDSS PI Carl Ayers. *Evidence Based Services Statewide Survey*. Sponsored by VDSS Division of Family Services.

CONCLUSION

All research approved by the IRB in SFY 2019 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.

Top priorities for SFY 2020 remain:

- Promoting use of the new CITI training program among VDSS and LDSS staff who are involved in departmental research;
- Helping current and new IRB members fulfill their training requirements through CITI;
- Updating IRB policies and procedures to be in compliance with the revised Common Rule that becomes effective January 1, 2019;
- Streamlining procedures and forms;
- Increasing the awareness of protecting human subjects across the Commonwealth; and
- Updating the VDSS IRB website.

SFY 2019 ANNUAL REPORT ON HUMAN RESEARCH
VDSS INSTITUTIONAL REVIEW BOARD
OCTOBER 2019

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. This report documents State Fiscal Year (SFY) 2019 activities of the VDSS human research committee, known as the Institutional Review Board (IRB).

BACKGROUND

The VDSS IRB is responsible for providing guidance and oversight to the human research protection program and for helping to maintain compliance with applicable laws, regulations, and policies. Specifically, the 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 VDSS IRB has the responsibility of protecting human subjects in studies that utilize or seek to gather information about VDSS clients and/or employees as well as local department of social services (LDSS) clients and/or employees. Human research activities reviewed by the IRB may be, but are not limited to, studies that are proposed, conducted and/or authorized by VDSS, the LDSS, VDSS/LDSS contractors, or VDSS-licensed facilities.

The IRB reviews research prior to implementation to ensure that the proposed research, first, protects the rights of clients and, second, maintains the privacy and confidentiality of information or data collected from participants. Using established regulatory criteria, the IRB may determine that a study: 1) satisfies criteria for being exempt from review, 2) is appropriate for expedited review, or 3) requires full board review. Generally, the IRB chair and/or one or two other IRB members conduct exemption determinations and expedited reviews. 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.

Research submitted to the IRB involves social or behavioral studies. Many of these studies entail evaluation of delivery of programs services and/or benefits to agency clients. Risk of physical harm is unlikely for these types of studies or evaluations. Most reviewed studies qualify as minimal risk. The potential harm associated with a minimal risk study focuses on issues of privacy, confidentiality, equable treatment, client informed consent and, to a 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 (USDHHS) 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) is effective through July 22, 2020 and is renewable at the end of the term. The IRB is also registered (# IORG0004422) with USDHHS.

The VDSS Office of Research and Planning (ORP) is responsible for administering the IRB and ensuring compliance with federal and state regulations regarding human subject research. Dr. Jeff Price, VDSS ORP Director, serves as the IRB Ombudsman. Dr. Eleanor Brown services as IRB Chair and Coordinator. The IRB is composed of ten voting members as described in Appendix B. Each member of the IRB **is** appointed by the VDSS Commissioner to serve a three-year term and VDSS IRB membership complies with all state and federal human research regulations. In SFY 2019, eight members were re-appointed to serve another three-year term. Two new members were appointed to serve in order to fill vacancies created by departing members.

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 and determine if all research activities comply with this policy prior to the commencement of the research. In cases of approval with conditions, require investigators to make modifications to the study prior carrying out any research activities.
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 execute its authority to observe or have a third party observe the consent process and the research.
7. Suspend or terminate approval of research not 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 will be reported promptly to the investigator and appropriate institutional official.
8. Obtain reports summarizing the findings of completed studies and publish summaries on the VDSS Public Website.

FISCAL YEAR 2019 IRB ACTIVITIES

Meetings of the VDSS IRB in SFY 2019

The IRB convened twice during the fiscal year, once on February 21, 2019 and again on April 9, 2019. At the meeting February 21st, the IRB conducted a full board review of IRB #2019-05 from Total Child Health (CHADIS), Baltimore MD. The Board had numerous questions about the study, and these issues were communicated to the PI submitting the research (Kerry Ann Bet MPH, CHES, Research Coordinator). The PI responded to these questions May 31, 2019, and the Board will review the proposed research again at the next meeting planned for September 2019. Questions and discussion by about this proposed research are included in minutes of the February 21st meeting found in Attachment C.

The IRB met again on April 9, 2019. No studies required full board review at this time however, the board reviewed studies approved to date, both exempt and expedited. Key topics of discussion for the board at this meeting included: final revisions to the Common Rule, specifically those related to concepts of Broad Consent and Limited Review; use of Reliance or Authorization Agreement; application of VDSS IRB Criteria for Review to studies before engaging the Board in a review of submission research. More detail of these discussion are provided in the minutes of the April 9th meeting found in Attachment C.

During SFY 2019, twenty-two (22) research studies came before the IRB. The IRB's actions are summarized below.

Studies approved as Exempt from IRB Review

The IRB determined eight (8) studies to be Exempt from Review. Federal (45 CFR 46 et seq.) and state (§32.1-162 and 22VAC40-890 et seq.) statutes describe several categories of research that do not require IRB review. However, the IRB determines if a research study meets the requirements for Exempt status. Studies submitted to the VDSS most often fall into two categories of exemption as defined in the statutes. The first category describes research using information about human subjects that is never linked (directly or indirectly) to any individual through personal identifiers. Furthermore, disclosure of the subject's information outside the research would not reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation. The second category describes research and demonstration projects that are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine public benefit or service programs.

Studies Approved under Expedited Procedures

- The IRB approved eleven (11) studies through Expedited Review Procedures. A study qualifies for expedited review if research activities (a) present no more than minimal risk to human subjects, and (b) involve only secondary analysis of existing data, documents, or records originally collected for non-research purposes. The VDSS IRB Chair and one other IRB member conduct expedited reviews. Of the eleven studies approved under Expedited Review, six (6) submissions consisted of Modifications to initially approved research and two were continuing reviews required by the initial IRB approval. Three studies were

approved for Initial Expedited Review however, one study was later withdrawn. The two remaining studies approved in SFY2019 are in progress and have strong VDSS agency sponsorship.

Studies Approved through Reliance or Authorization Agreement

The IRB approved three (3) studies by Reliance Agreement, also referred to as an Authorization Agreement. A reliance agreement is a contract between IRBs from different institutions involved in the same human research study, whereby one institution agrees to cede IRB oversight and monitoring to the other IRB. This provides a reasonable method of joint or cooperative review that reduces duplication of effort and improves efficiency. All Reliance Agreements entered into by VDSS are reviewed in detail by the VDSS IRB chair and approved by the VDSS Commissioner. Criteria for Reliance Agreements, as discussed by the VDSS IRB at their April 2019 meeting include: known and reputable research organization or university; clear and engaged PI and institutional individuals accessible to respond to VDSS IRB questions when needed; thorough review of all study materials of the initial submission to the relying institution by the VDSS IRB Chair. Reliance Agreements undertaken by VDSS in SFY2019 were with the following entities:

- ICF, PI Christine Leicht and VDSS PI Carl Ayers. *Prenatal Alcohol and Other Drug Exposures in Child Welfare (PAODE_CW)* sponsored by the US DHHHS, Children's Bureau.
- Urban Institute, PI Kristin Blagg, and VDSS PI Jeff Price. *How do students us social safety net supports before, during, and after college enrollment?* Sponsored by the Virginia Division of Benefit Programs and Office of Research and Planning.
- University of Richmond, PI Lisa Jobe-Sheilds and VDSS PI Carl Ayers. *Evidence Based Services Statewide Survey*. Sponsored by VDSS Division of Family Services.

CONCLUSION

All research approved by the IRB in SFY 2019 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. In SFY2019, several studies will close out and final reports posted on the IRB Internet site.

Top priorities for SFY 2019 include:

- Promoting use of the new CITI training program among VDSS and LDSS staff who are involved in departmental research;
- Helping current and new IRB members fulfill their training requirements through CITI;
- Updating IRB policies and procedures to be in compliance with the revised Common Rule that becomes effective January 1, 2019;
- Streamlining procedures and forms;
- Increasing the awareness of protecting human subjects across the Commonwealth; and
- Updating the VDSS IRB website.

APPENDIX A: STATE FISCAL YEAR 2019 STUDY DETAILS

STUDIES APPROVED BY EXPEDITED PROCEDURES

Wendy's Wonderful Kids Post-Adoption Study IRB #2014-04	
Type of Submission:	Continuation
Type of Review:	Expedited Review
Agency Sponsor:	Division of Family Services
Principal Investigator:	Karin Main, MS
PI Affiliation:	Child Trends
Initial Date Approved:	3/26/2014
Modification date:	9/8/2017
Date Submitted:	9/5/2018
Date Approved:	10/18/2018
Date Approval Ends:	10/19/2019
Status:	Ongoing
Description: This study aims to assess the well-being of older children adopted through the Wendy's Wonderful Kids (WWK) adoption recruitment program. Participants are young adults who were adopted from foster care at the age of 8 years or older and were placed in adoptive homes through the WWK program. The study data collection will end by December 2018. Young adults who were adopted have been invited to participate in an in-person interview as they reach their 18th birthday. The interview assesses their well-being and any challenges faced in young adulthood, including disruption of their adoption. The PI obtained a Certificate of Confidentiality dated 1/27/2014 from the National Institutes of Health, Department of Health and Human Services. As of 9/5/18, five VDSS young adults have been interviewed.	

Evaluation of SNAP Employment and Training Pilots2016-06	
Type of Submission:	Continuation
Type of Review:	Expedited Review
Agency Sponsor:	Division of Benefit Programs
Study Funder:	USDA FNS
Principal Investigator:	James Mabli, PhD
PI Affiliation:	Mathematica Policy Research
Initial Date Approved:	2/11/2016
Date Submitted:	12/7/2018
Date Approved:	1/10/2019
Date Approval Ends	1/10/2020
Status:	Ongoing
Description: Mathematica Policy Research is evaluating 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 have the greatest impact on increasing employment among SNAP clients.	

Longitudinal Infant and Family Environment (LIFE) Study 2018-02	
Type of Submission:	Continuation and Modification
Type of Review:	Expedited Review
Agency Sponsor:	Division of Family Services
Study Funder:	VDSS MOA
Contract Number:	FAM-17-084
Principal Investigator:	Sunny H. Shin, PhD
PI Affiliation:	Virginia Commonwealth University
Initial Date Approved:	9/19/2017
Date Submitted:	8/29/2018
Date Approved:	9/5/2018
Date Approval Ends	9/30/2019
Status:	Ongoing
Description: The Longitudinal Infant and Family Environment (LIFE) Study (a.k.a. Baby Box Project) examines whether or not enhanced patient education about sudden infant death syndrome (SIDS)/sudden unexpected infant death (SUID) and safe sleep environment, as well as use of a baby box, decreases unsafe sleep practices at home. A total of 1,100 women who give birth at Children's Hospital of Richmond are recruited for this study. Hospital personnel (e.g., nurses, residents/interns, medical students) conduct discharge education with patients and are involved in recruiting potential participants for the study. Patients are randomly assigned to either the experimental (study) group or the control group (550 in each group).	

Procedural Justice-Informed Alternatives to Contempt (PJAC) Demonstration 2018-06	
Type of Submission:	Modification 1
Type of Review:	Expedited Review
Agency Sponsor:	Division of Child Support Enforcement
Study Funder:	US Office of Child Support Enforcement (OCSE), ACF, US DHHS
Contract Number:	DSA
Principal Investigator:	Cindy Redcross
PI Affiliation:	MDRC
Initial Date Approved:	6/18/2018
Date Submitted:	6/28/2018
Date Approved:	8/2/2018
Date Approval Ends	NA
Status:	Ongoing
Description: The first modification adds an operations visit during which the evaluation team gathers background information and assesses early operations (e.g., early check on the random assignment process, delivery of PJAC services, use of the project management information system, and understanding counterfactual services). Information gathered during this visit will help inform development of research instruments for the implementation study component of the PJAC evaluation.	

Procedural Justice-Informed Alternatives to Contempt (PJAC) Demonstration 2018-06	
Type of Submission:	Modification 2
Type of Review:	Expedited Review
Agency Sponsor:	Division of Child Support Enforcement
Study Funder:	US Office of Child Support Enforcement (OCSE), ACF, US DHHS
Contract Number:	DSA
Principal Investigator:	Cindy Redcross
PI Affiliation:	MDRC
Initial Date Approved:	6/18/2018
Date Submitted:	10/23/2018
Date Approved:	10/30/2018
Status:	Ongoing
The second modification provides for pretesting the participant survey instrument. To ensure that the questions posed make sense and are clearly understood by the PJAC participant population, MDRC will pretest the instrument with a few noncustodial parents randomly assigned during the first several months of study enrollment.	

Procedural Justice-Informed Alternatives to Contempt (PJAC) Demonstration 2018-06	
Type of Submission:	Modification 3
Type of Review:	Expedited Review
Agency Sponsor:	Division of Child Support Enforcement
Study Funder:	US Office of Child Support Enforcement (OCSE), ACF, US DHHS
Contract Number:	DSA
Principal Investigator:	Cindy Redcross
PI Affiliation:	MDRC
Initial Date Approved:	6/18/2018
Date Submitted:	1/31/2019
Date Approved:	3/5/2019
Status:	Ongoing
Description: The third modification approved implementation of site visits that include: 1) observations of public court proceedings: 2) interviews with child support caseworkers, managers, agency legal staff, and management staff at referral partner organizations; and 3) case file reviews. No sampled parent participants are interviewed.	

Vision 21 Linking Systems of Care Listening Tour 2018-12	
Type of Submission:	Modification 3
Type of Review:	Expedited Review
Agency Sponsor:	VDSS, Community and Volunteer Services, Office of Family Violence
Study Funder:	Office for Victims of Crime, US Dept of Justice
Principal Investigator:	Anna Cody
PI Affiliation:	VDSS, Community and Volunteer Services, Office of Family Violence
Initial Date Approved:	5/24/2018
Prior Modification date:	6/22/2018
Date Submitted:	9/12/2018
Date Approved:	9/28/2018
Status:	Completed
Description: Two prior modifications to the project were approved in SFY2018. One allowed for tracking distribution of gift cards while keeping the anonymity of participants. The second modification provided for changes of venue and new sessions to be posted where potential participants could get the updated information, again while maintaining anonymity of participants. The third modification allowed for the study to expand the venues where recruitment and study activities could occur, specifically, advertising upcoming listening sessions and holding listening sessions at youth venues and conferences for youth who left foster care.	

Vision 21 Linking Systems of Care Listening Tour 2018-12	
Type of Submission:	Modification 4
Type of Review:	Expedited Review
Agency Sponsor:	VDSS, Community and Volunteer Services, Office of Family Violence
Study Funder:	Office for Victims of Crime, US Dept of Justice
Principal Investigator:	Kim Barbarji
PI Affiliation:	VDSS, Community and Volunteer Services, Office of Family Violence
CoPI/Study Coordinator:	Laurie Crawford
CoPI/Study Coordinator Affiliation:	VDSS, Community and Volunteer Services, Office of Family Violence
Initial Date Approved:	5/24/2018
Prior Modification date:	9/28/2018
Date Submitted:	1/3/2019
Date Approved:	1/23/2019
Status:	Completed
Description: This modification changes the PI for the study from Anna Cody to Kim Barbarji. As with the former PI, Ms. Barbarji reports to the project manager for the Vision 21 program, Laurie Crawford. In addition, Ms. Barbarji has served as co-researcher on the project from the beginning, is highly qualified as a trainer and facilitator, and has completed all required IRB training. The listening sessions will continue to follow the same procedures and protocol as described in prior submissions, modifications, and approvals.	

To what extent does a history of sexual abuse affect the permanency outcomes of foster youth? 2019-02	
Type of Submission:	Initial Review
Type of Review:	Expedited Review
Agency Sponsor:	Division of Family Services
Principal Investigator:	Takyra Jefferson
PI Affiliation:	VCU School of Social Work
Initial Date Approved:	
Date Submitted:	10/22/2018
Date Approved:	12/21/2018
Status:	PI Discontinued
Description: Subjects in the study, ages 13-17 with a history of child sexual abuse, will be identified from existing administrative records in the VDSS Child Welfare Case Management System (OASIS) provided through a DSA with the PI. Specifically, data from one agency within each of the five LDSS regions will be analyzed to determine if there is a relationship between clients with history of child sexual abuse and permanency outcomes. There is no direct interaction between the PI and subjects; no access by the PI to subjects' personal identifying information; and all participant data will be stored in an encrypted database to safeguard confidentiality and privacy.	

Linking System of Care Process and Outcomes Evaluation IRB# 2019-08	
Type of Submission:	Initial Review
Type of Review:	Expedited Review
Agency Sponsor:	VDSS Office of Family Violence, Division of Community and Volunteer Services
Principal Investigator:	Laurie Crawford
PI Affiliation:	VDSS Office of Family Violence, Division of Community and Volunteer Services
Date Submitted:	3/20/2019
Date Approved:	4/30/2019
Status:	Ongoing
Description: In 2015, the U.S. Department of Justice's Office for Victims of Crime (OVC) funded the Commonwealth of Virginia to conduct a Linking Systems of Care (LSC) Demonstration Project. Through this project, the Commonwealth of Virginia was given an opportunity to ensure that children and youth are (a) screened for victimization and (b) provided comprehensive and coordinated services to fully address their needs. Initially, ICF was hired to perform a national evaluation of the Project, with oversight from the National Institute of Justice. In late 2018, however, OVC eliminated federal funding for the ICF evaluation, and these responsibilities transferred to the VDSS Office of Family Violence as the state Project's lead agency. To fulfill this responsibility, the evaluation plan includes two surveys to be administered at two different points in time. One survey will be administered to youth victims or their parents, and another survey will be administered to child/youth service providers. Each of these two surveys will be administered before and after implementation of the tools developed by the LSC Project. Analysis will compare responses, pre and post, to determine the degree and direction of change due to the intervention.	

Child Welfare Workers' Attitudes, Evidence-Based Practice, and Placement Decisions Regarding Kinship 2019-10	
Type of Submission:	Initial Review
Type of Review:	Expedited Review
Agency Sponsor:	VDSS Division of Family Services
Principal Investigator:	Gardenella Green
PI Affiliation:	Ethelyn R. Strong School of Social Work, Norfolk State University
Date Submitted:	1/17/2019
Date Approved:	4/2/2019
Date Approval Ends	12/31/2020
Status:	Ongoing
Description: To date, very few studies have examined child welfare workers attitudes about kinship care, no studies in Virginia have explored public child welfare workers attitudes on this topic, nor has research to date examined relationships between evidence based practice and public child welfare workers' attitudes towards kinship care. The purpose of the study is to examine these associations. Information will be gathered through an anonymous questionnaire/survey that examines: 1) public child welfare workers' attitudes toward kinship care measured using the Measuring Professional Attitudes on Kinship [MPAK (Briseboise, Kernsmith, & Carcone, 2013)]; 2) their barriers to using evidence-based practice using author approved revisions to the Evidence Based Practice Questionnaire [EBP (Jette et. al., 2003)], and their placement decisions. The survey will be administered both online and in-person. The targeted sample size for this study is 200 public child welfare workers. There is minimal risk associated with accidental disclosures of PII.	

STUDIES APPROVED BY EXEMPT DETERMINATION

Title IV-E Child Welfare Stipend Program (CWSP) Graduate Exit Survey 2019-03	
Type of Submission:	Initial Review
Type of Review:	Exempt Determination
Reason for Exemption	45 CFR 46.101(b) (2)(3) and (5)
Agency Sponsor:	Division of Family Services
Principal Investigator:	Em Parente
PI Affiliation:	VDSS Division of Family Services
Date Submitted:	10/18/2018
Date Approved:	10/26/2018
Status:	Ongoing
Description: The goal of this survey research is to determine if and how the CWSP is meeting the overarching goals of recruiting and training students committed to working in public child welfare, thereby increasing the retention and professionalization of our local department of social services (LDSS) workforce. The data gathered through the exit survey will serve to help guide further development and improvement of the CWSP, as well as fulfill federally approved program plan obligations.	

Youth Exit Survey Initiative 2019-06	
Type of Submission:	Initial Review
Type of Review:	Exempt Determination
Reason for Exemption	45 CFR 46.101(b) (2)(3) and (5).
Agency Sponsor:	Virginia Commission on Youth and VDSS Division of Family Services
Principal Investigator:	Em Parente
PI Affiliation:	VDSS Division of Family Services
Date Submitted:	10/23/2018
Date Approved:	10/26/2018
Status:	Ongoing
Description: The 2017 Virginia's General Assembly directed the Virginia Department of Social Services (VDSS) in coordination with the Virginia Commission on Youth (VCoY) to create a survey that asks questions about the relationships, resources, activities, and overall experiences of youth who have been in foster care. Survey response data may be used to inform policy and program development efforts in Virginia's foster care system. The primary goal of this survey is to gather feedback from youth who have been in foster care. This feedback may facilitate evaluation of the Virginia foster care system's overarching goals of educational stability, normalcy, youth involvement in case planning, and high-quality service provision.	

Youth Exit Survey Initiative 2019-06	
Type of Submission:	Modification 1
Type of Review:	Exempt Determination
Reason for Exemption	45 CFR 46.101(b) (2)(3) and (5).
Agency Sponsor:	Virginia Commission on Youth and VDSS Division of Family Services
Principal Investigator:	Em Parente
PI Affiliation:	VDSS Division of Family Services
Initial Date Approved:	10/23/2018
Date Submitted:	11/6/2018
Date Approved:	11/8/2018
Status:	Ongoing
Description: For the Pilot study, the timeline for initial local department of social services (LDSS) worker notification is changed from 120 days to 60 days. In addition, gift cards will not be provided to subjects who participate in the Pilot Survey.	

Youth Exit Survey Initiative 2019-06	
Type of Submission:	Modification 2
Type of Review:	Exempt Determination
Reason for Exemption	45 CFR 46.101(b) (2), (3) and (5).
Agency Sponsor:	Virginia Commission on Youth and VDSS Division of Family Services
Principal Investigator:	Em Parente
PI Affiliation:	VDSS Division of Family Services
Initial Date Approved:	10/23/2019
Prior Modification Date:	11/8/2018
Date Submitted:	1/30/2019
Date Approved:	2/19/2019
Status:	Ongoing
Description: Modifications allowed for an extension of the Pilot Survey to a second region of Virginia, the Piedmont Region in the pilot phase (January through June 2019) of the Youth Exit Survey Initiative. VDSS anticipates that the expansion of the pilot phase, to include 25 Piedmont Region agencies, will double the number of eligible youth and thus provide additional survey response data.	

STREAMinc3 Curriculum Pilot and Evaluation 2019-07	
Type of Submission:	Initial Review
Type of Review:	Exempt Determination
Reason for Exemption	45 CFR 46.101(b)(1)
Agency Sponsor:	Division of Child Care and Early Childhood Development
Study Funder:	Division of Child Care and Early Childhood Development
Principal Investigator:	Amanda Williford
PI Affiliation:	University of Virginia
CoPI/Study Coordinator:	Rebecca Shaffer
CoPI/Study Coordinator Affiliation:	VDSS Division of Child Care and Early Childhood Development
Date Submitted:	3/4/2019
Date Approved:	3/5/2019
Status:	Ongoing
Description: The Study Protocol describes creation of an archival dataset using information collected over the course of a pilot and evaluation of a new birth-to-age-5 comprehensive early childhood education curriculum called STREAMin3. The study does not recruit teachers or students to be a part of the evaluation – if they are in the programs who have elected to use STREAMin3 curriculum, then information will be collected as part of the curriculum and evaluation.	

Virginia Workload Measures Study 2019-09	
Type of Submission:	Initial Review
Type of Review:	Exempt Determination
Reason for Exemption	45 CFR 46.101(b)(5)
Agency Sponsor:	VDSS Office of Research and Planning
Study Funder:	VDSS
Contract Number:	VDSS/ORP-18-208
Principal Investigator:	Robert Morris
PI Affiliation:	Center for Applied Innovation, LLC
CoPI/Study Coordinator:	Brooke Schaab
CoPI/Study Coordinator Affiliation:	Center for Applied Innovation, LLC
Date Submitted:	2/25/2019
Date Approved:	2/25/2019
Status:	Ongoing
Description: The Virginia Department of Social Services (VDSS) contracted with the Center for Applied Innovation, LLC (CAI) to conduct a workload measures study. Using an innovative approach use, CAI will conduct a comprehensive analysis and development of a workload measures tool for benefit and family services programs delivered by the 120 local departments of social services (LDSS). Methods: CAI will collect data in the form of policies, procedures, processes, program information, the organization, processes, current and future needs and empirical data including workload measures (required and non-required time), time required to work cases, time required to complete specific tasks on cases, environmental and operational factors impacting workload, and requirements for a Workload Analysis Tool.	

2019 Foster, Adoptive and Kinship Parent Survey 2019-11	
Type of Submission:	Initial Review
Type of Review:	Exempt Determination
Reason for Exemption	45 CFR 46.101(b)(5)
Agency Sponsor:	Division of Family Services
Principal Investigator:	Em Parente
PI Affiliation:	VDSS Division of Family Services
Date Submitted:	2/28/2019
Date Approved:	3/6/2019
Status:	Ongoing
Description: The goal of the study is to gain insight about training and other supports that are provided to foster, adoptive and kinship parents in Virginia. Using a self-administered survey, the study will gather the following information: 1) Baseline information for specific parent involvement in the child welfare system; 2) Attendance, satisfaction levels and future interest as it relates to trainings and support services for resource parents; 3) Any limitations experienced by resource parents receiving support services; and 4) Satisfaction with LDSS workers related to communication, transition periods, and specific service needs. Results of the survey will be presented to VDSS, LDSS, and community stakeholders. Results may be published as standalone data or within the context of the larger program evaluation and/or reporting documents. Results or collected information will not include identifiable information of any participants	

TANF Noncustodial Parent Employment Program Pilot 2019-16	
Type of Submission:	Initial Review
Type of Review:	Exempt Determination
Reason for Exemption	45 CFR 46.101(b)(5)
Agency Sponsor:	Division of Child Support Enforcement and Division of Benefit Programs
Study Funder:	VDSS Division of Benefit Services
Principal Investigator:	Mark Golden
PI Affiliation:	VDSS Division of Benefit Services
CoPI/Study Coordinator:	Monique Majeus
CoPI/Study Coordinator Affiliation:	VDSS Division of Benefit Services
Date Submitted:	4/26/2019
Date Approved:	5/13/2019
Status:	Ongoing
Description: The purpose of the TANF Noncustodial Parent (NCP) Employment Program Pilot is to assist low-income noncustodial parents in the Commonwealth of Virginia to create pathways out of poverty, progress to self-sufficiency, pay off child support debts, and pay child support on a consistent basis. The local agency Employment Services Workers will provide NCPs with employment and participation services. The specific research methods applicable to this project, both the implementation and evaluation of the pilot, will include administrative data about subjects' participation as well as outcome data on successful program completion and child support payments made consistently. Participation is voluntary; however individuals eligible to participate who decline to join the project will be served by the VDSS Department of Child Support Enforcement in the normal process for non-compliant parents.	

Prevention and CPS On-going Case Practice Survey 2019-17	
Type of Submission:	Initial Review
Type of Review:	Exempt Determination
Reason for Exemption	45 CFR 46.101(b)(5)
Agency Sponsor:	Division of Family Services
Study Funder:	NA
Contract Number:	NA
Principal Investigator:	Elizabeth Overall
PI Affiliation:	VDSS Division of Family Services
Date Submitted:	5/10/2019
Date Approved:	5/10/2019
Status:	Completed
Description: The Family First Prevention Services Act, which was signed into law in February 2018, includes a significant funding reform: the ability to access Title IV-E federal funds for evidence-based services before a child enters foster care, which is typically when a family is working with a CPS on-going or prevention case manager in the local department of social services. A survey was administered to DFS advisory committee members, as well as to all 120 LDSS in the Commonwealth, to be completed voluntarily. No personal identifying information (PII) will be included in the survey or survey responses. Results from the survey will inform the committee members and VDSS on current practices that occur across the state, which will guide the work moving forward.	

Diligent Recruitment Survey 2019-19	
Type of Submission:	Initial Review
Type of Review:	Exempt Determination
Reason for Exemption	45 CFR 46.101(b)(5)
Agency Sponsor:	Division of Family Services
Study Funder:	NA
Contract Number:	NA
Principal Investigator:	Elizabeth Lee
PI Affiliation:	VDSS Division of Family Services
Date Submitted:	6/28/2019
Date Approved:	6/28/2019
Status:	Completed
Description: Legislation was passed in Virginia's 2019 General Assembly that required more intensive efforts to be made towards recruitment and retention efforts, and several positions were created to support the work. In addition, one of the strategies outlined in Virginia's Five Year Child and Family Services Plan (CFSP) is to address permanency by creating a more comprehensive Diligent Recruitment Plan that addresses the root cause issues and identifies specific strategies to implement over the next five years. The purpose of this survey is to have some understanding of how local departments of social services (LDSS) collect data, share resources, support foster families and identify reasons for siblings not being placed in the same home.	

STUDIES APPROVED BY RELIANCE AGREEMENT

Evidence Based Services Statewide Survey 2019-05	
Type of Submission:	Initial Review
Type of Review:	Reliance Agreement with OHRP FWA #00002622
Agency Sponsor:	Division of Family Services
Principal Investigator:	Lisa Jobe-Sheilds
PI Affiliation:	University of Richmond
CoPI/Study Coordinator:	Carl Ayers
CoPI/Study Coordinator Affiliation:	VDSS Division of Family Services
Date Submitted:	10/16/2018
Date Approved:	11/7/2018
Status:	Ongoing
Description: The project will gather information regarding current use of evidence-based practices in child welfare settings in Virginia. In addition, the project will also evaluate provider, broker, and senior leader attitudes towards evidence-based treatment in general. Overall, these two purposes will provide pertinent information for the implementation of the Family First Prevention Services Act, which was signed into federal law February 2018, and will be implemented in October 2019.	

Prenatal Alcohol and Other Drug Exposures in Child Welfare (PAODE-CW) Study 2019-13	
Type of Submission:	Initial Review
Type of Review:	Reliance Agreement with ICF (OHRP FWA #00000845)
Agency Sponsor:	Division of Family Services
Study Funder:	US DHHS, Children's Bureau
Contract Number:	#HHSP233201500133/HHSP23337007T
Principal Investigator:	Christine Leicht
PI Affiliation:	ICF
CoPI/Study Coordinator:	Carl Ayers
CoPI/Study Coordinator Affiliation:	VDSS Division of Family Services
Date Submitted:	3/5/2019
Date Approved:	4/24/2019
Status:	Ongoing
Description: The study objective is to gather information on current policies and practices in place in child welfare agencies related to the identification of children with prenatal substance exposure and their families. The purpose is not to evaluate individual state agencies, or any local agencies in your jurisdiction, nor is it to monitor compliance. Four to six local child welfare agencies in Virginia will participate in a site visit with 2-3 project team members and share policy documents related to identifying children with prenatal substance exposure. A high-level summary of findings will be provided that may be used by state or local agencies to develop future resources to help child welfare agencies in their work on this topic.	

How do students us social safety net supports before, during, and after college enrollment? 2019-12	
Type of Submission:	Initial Review
Type of Review:	Reliance Agreement with Urban Institute OHRP FWA #0189
Agency Sponsor:	Division of Benefit Programs and Office of Research and Planning
Principal Investigator:	Kristin Blagg
PI Affiliation:	Urban Institute
CoPI/Study Coordinator:	Jeff Price
CoPI/Study Coordinator Affiliation:	VDSS Office of Research and Planning
Date Submitted:	3/4/2019
Date Approved:	4/15/2019
Status:	Ongoing
Description: The majority of this research uses data from the Virginia Longitudinal Data System (VLDS). The study examines public benefits receipt and financial security among all college students before, during, and after they enroll in college. The study population consists of individuals who were enrolled in SNAP, TANF, or VIEW during the study period, and/or attended public post-secondary institutions in Virginia. Following request and review, the VLDS provides de-identified data to researchers that combines data from ten state agencies including VDSS, VEC, VDOE, SCHEV, and VCCS. In addition to the data analysis, researchers will conduct phone and in-person interviews with financial aid officers in Virginia community colleges, as well as those who administer safety net programs in Virginia. For interviews with administrators, researchers will know the individual's name, but will not collect confidential or sensitive data from them. The purpose of the interview is to provide background information on policies and procedures. Waiver of informed consent is used as the project meets the four criteria outlined by federal guidelines.	

APPENDIX B: VDSS IRB MEMBERSHIP FOR SFY 2019

VDSS INSTITUTIONAL REVIEW BOARD MEMBER ROSTER SFY2019			
Last Name	**First Name**	**Highest Educational Degree(s)**	**Institutional Affiliation (Position Title)**
Brown[1]	Eleanor	MSW, MPH, PhD; Maternal and Child Health	VDSS, Office of Research and Planning (Research Associate Senior)
Cleary	Hayley	PhD, MPP**;** Developmental Psychology; Public Policy	VCU Wilder School of Government and Public Affairs (Associate Professor)
Disse[2]	Mary	BA; Psychology Post-Baccalaureate Certificate in Information Systems	VDSS, Division of Technology (Project Manager)
Hawley	Carolyn	PhD, CRC**;** Health Related Sciences/Rehabilitation Leadership; Certified Rehabilitation Counselor,	VCU Dept of Rehabilitation Counseling (Associate 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)
Minesh Amin	Dhara	MS; Criminal Justice	Department of Juvenile Justice (Research Analyst & Coordinator of External Research)
Parente	Em	MSW, LCSW, PhD; Social Work	VDSS, Division of Family Services (Program Manager)
Price[3]	Jeff	PhD; Economics	VDSS Office of Research and Planning (Director)
Temoney[2]	Tamara	MSW, PhD; Public Policy and Administration	Hanover County Department of Social Services (Assistant Agency Director)
Wike	Traci	MSW, PhD; Social Work	VCU School of Social Work (Associate Professor)
[1]IRB Chair and Administrator; [2]Nonscientific member; [3]IRB Ombudsman			

APPENDIX C: MINUTES OF IRB MEETINGS FOR SFY2019

MINUTES OF VDSS IRB MEETING FEBRUARY 2019

Date and Time : 2/21/2019
Location: VDSS, 801 East Main Street Richmond, VA, 15th floor Conference Room
Members Present: Eleanor Brown, Hayley Cleary, Mary Disse, Gail Jennings, Erika Jones-Haskins, Dhara Amin, Tamara Temoney

The Chair reminds 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.

OLD BUSINESS:
Updates to board membership since the last meeting in June 2018 were presented. These include the resignation of Jessica Schneider (VA-DJJ) after several years of generous service to the VDSS IRB; and based on her recommendation an appointment to the IRB was extended to and accepted by Dhara Minesh (VA-DJJ) in September 2018. Reappointments were also extended and accepted in September for Em Parente (VDSS), Erika Jones-Haskins (VA-DBHDS), Gail Jennings (VDSS), Jeff Price (VDSS), Mary Disse (VDSS), and Tamara Temoney (Hanover LDSS).

Jeff Price, IRB Ombudsman, attended a substantial portion of the meeting. Dr. Traci Wike, Associate Professor at the VCU School of Social Work attended the meeting as an observer. The IRB anticipates filling a vacancy, set to occur in March 2019, with the appointment of Dr. Wike.

FULL BOARD REVIEW:
The IRB began a full board review of IRB Study #2019-05 Titled - A clinical support system for primary care to address family stress. Sponsor/Funder is NIH and Investigator is Barbara Howard, MD. Appendix A provides details about the discussion and study.

OTHER REVIEWS:
Time did not allow for discussion of other studies, approved to date in SFY2019 under expedited or exempt review. The topic will be added to Old Business for the next meeting.

NEW BUSINESS:
Suggestions for future meetings included meeting quarterly, and a tentative date for the next meeting was set for April 9, 2019. The time of 11am – 1pm was favorable, and the location adequate. Only one board member needs parking and the remaining can either take a VCU bus or walk from their respective offices.

Time did not allow for discussion of the Revised Common/Final Rule. The topic will be added to Old Business for the next meeting.

ADJOURNED TIME:
The meeting lasted more than the 1½ hours reserved, and continued until 1:00pm.

VDSS IRB MEETING FEBRUARY 2019
Attachment A: Full Board Review

STUDY TITLE: A Clinical Support System for Primary Care to Address Family Stress
VDSS IRB #: 2019-05
SPONSOR/FUNDER: NIH
INVESTIGATOR: Barbara Howard, MD

DISCUSSION & QUESTIONS:
The items summarized below were so extensive that the Board determined that questions should be sent to the PI, and responses provided, before the IRB will move forward with the review.

- VDSS needs to review the full study, for suggestions and questions.
- What elements in the Referral – limited fields – see what they ask for? VDSS should specify the variables. How broad a list of individuals – victims, perpetrator, associated non-victims, non family perpetrators (boyfriends)? What level of detail about the CPS referral… minimally necessary?
- Do we go back three years and then forward up to three years?
- Script for the consent process. FAQs from participants. Need a more complete consent form, may not be enough for the possible risks to a parent/partner or child. Potential seriousness of responses to questions, for example if one discloses domestic violence, child maltreatment, etc. what happens to that information.
- Needs to conform to new 2018 Final Rule. What about Broad Consent… future secondary data.
- Does the consent for the child signed by the mom, but allegation comes on the child
- No one for participant to call about CPS referral.
- No one from research on-site.
- Is this really minimal risk? Page 9 in protocol. Questions could
- How frequently will they submit client names/ids? Monthly, quarterly, other.
- What happens after they identify a CPS service
- Two separate consents? Consent for survey vs consent to share for referrals, receive clinical intervention… what if one refuses clinical intervention.
- Mandated reporter is specified.
- Can we get a copy of the MedStar approval documents?
- What if any is the financial incentive for participants, and referrals. Need more detail about financial aspects.
- How are the multiple measures (Grant document) being used? What is typical in clinical practice and what are extra questionnaires not typical.

- How can someone pull out of study… will all their data be pulled, i.e. the memory book, where does that live and is it secure. How long will these data last?
- Which part of this is clinical practice and how much is research.
- Intimate partner violence, how would you proceed with both parents/partners in the room?
- How would a partner complete the online survey – is there a mobile app?
- Consent required elements needed: top of form states it is research; need to be very specific about which part is being consented to; there are risks. Very intrusive questions; "…A few extra questions …" need to describe the many questions, questions before in waiting room, memory book, etc. What supports are provided when one has a traumatic moment during the process, either via PTSD or actual current experiences.
- Is the waiting room of a doctors office sufficiently privacy? What options are provided?
- Letter of support that indicates data request portion is doable.
-
- **DECISION AND VOTING: NA**

MINUTES OF VDSS IRB MEETING APRIL 2019

DATE: **April 9, 2019**
TIME: **11:00am – 1:00pm**
LOCATION: **VDSS, 801 East Main Street Richmond, VA, 23219**

MEMBERS PRESENT: Carolyn Hawley (call-in), Dhara Amin, Eleanor Brown, Erika Jones-Haskins (call-in), Gail Jennings, Hayley Cleary, Mary Disse, Traci Wike.

The meeting was called to order at 11:12 am. Members introduced each other, and the chair introduced Traci Wike, the newest member of the VDSS IRB. Jeff Price, Ombudsman, arrive at approximately 11:30 am.

The Chair reminds 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.

OLD BUSINESS

Minutes of VDSS IRB Meeting 2/21/2019 were emailed to the board. Members are encourage to email the chair if there are any adjustments, concerns, or revisions. Otherwise the minutes were approved.

At the last VDSS IRB meeting, the board had numerous questions for the PI, Barbara Howard with Total Child Health, Baltimore, MD, of the research study titled to "A clinical support system for primary care to address family stress". These questions were submitted to Dr. Howard on March 15, following the February Board meeting. The IRB chair is waiting for a response, and will share with the board when received for further review.

The board was also sent a copy of the 2018 Annual Report to the General Assembly. This report is prepared in August and submitted to the General Assembly in the fall of each year. The chair will get the report to the IRB more promptly in the future.

Revisions to the final Common Rule

There was not sufficient time in the February board meeting to review the federal changes to the Common Rule, also known as the Final Rule. While a great deal of the revisions for the Final Rule concern bio-specimens and specific medical issues, two revisions impact the VDSS IRB – provisions for Limited Review and Broad Consent. The chair provided documents related specifically to changes relevant to VDSS: §46.116 General requirements for informed consent; and Overview of the Final Rule Revisions (prepared by chair Ebrown from Source: CITI Last update June 2018)

The chair provided a brief overview of the revisions that provide for *Broad Consent* is an alternative to informed consent. The final rule includes multiple references of items still required for Broad Consent. Clients must sign off, before receiving services, that their data can be used for research. This consent appears to include the same information required for existing Informed Consent (e.g. explain research, risks, participation voluntary, etc.).

The board realized that more review and discussion will be needed for the VDSS IRB to use Broad Consent. At this time there is no requirement however, for IRB's to use Broad Consent. It is an alternative to be used as determined by the IRB. Discussion points included:

- Issues of consent for foster care children remain, unless the bio parent provides consent when the child is removed from their home. Due to the nature of this event, voluntary consent is not realistic.
- Based on the wording in the Final Rule, clients would have to sign Broad Consent for their data to be used for research purposed when they apply for services/benefits. Again the voluntary nature of this practice is unrealistic.
- Tracking in administrative data would be both unwieldy and provide biased data on which to base any research conducted.
- Broad consent includes data with PII and would have to be introduced at the beginning of starting service/benefit.
- Consent is obtained at the time of intervention. Participation in a program is the intervention, however the intervention of the research may be an enhanced intervention. So could/should the consent only occur when the "enhanced intervention" is under study?
- Would clients sign a document that says "I agree that information to manage by this program may be used for secondary analysis of this program"?
- For benefit programs, what consent is asked for/provided? "I am providing my information to you to conduct the program" should we also ask for "consent for conducting some other aspect of the program"? Very confusing to the client.
- What time period would broad consent apply? How long will you keep data? How will it be destroyed?
- Don't we want the IRB to still determine if the use of these data is OK with the client, at the time the study is being conducted as opposed to any earlier Broad Consent?
- May not come to a final decision today. But need to think about. Should/could clients voluntarily refuse to sign? How can it be truly voluntary, as there is coercion implied in the power dynamic of the services?
- While this is included in the Final Rule, is the VDSS IRB required to apply Broad Consent? Seems it can be used as an alternative to informed consent, but doesn't seem required.
- We will need to identify/understand what uses of broad consent make sense for studies applicable for VDSS IRB review.
- What are the implications when broad consent provides names or other PII and a research study wants to link these data to other datasets with PII?
- Perhaps the VDSS IRB should wait until there is more experience with agencies using Broad Consent before making any decisions.
- At this time, when we do provide PII, the VDSS IRB and any related Data Sharing Agreement is approached very carefully and thoughtfully, with multiple eyes on any agreement.
- How would Broad Consent impact our responsibilities to licensed facilities and employees? Could a Broad Consent be applied to an employee at the time of hire, and would this truly be voluntary?

- There are existing laws and regulations about child protective services data and how long it can be maintained. Would procedures relative to retention would this broad consent apply.
- At this time, no researcher has applied to the VDSS IRB asking to use Broad Consent. And it is within the VDSS IRB's responsibility/authority to decline the use of Broad Consent.
- The chair asked for a motion to study the use of Broad Consent. Members' response was to wait until such time as a request for review was submitted. It is was determined by the board to withhold voting on the issue of Broad consent and wait until we have an actual study submitted. The chair will, in the meantime, track any new information about Broad Consent and its use by other researchers and organizations.

Related to, but distinct from, Broad Consent is the provision in the Final Rule for *Limited Review*. Again the Board had questions and discussion about the topic, agreeing that more information and review were needed to make any decisions about it's applicability for VDSS. Discussion points included:

- Does a Limited Review only apply when Broad Consent is used?
- What are the pros and cons of using Limited Review instead of Exempt Determination or Expedited Review
- Currently Studies approved by Exempt Determination are reviewed by the chair, studies approved by Expedited Procedures are reviewed by the chair and one other board member.
- The VDH IRB defines an Expedited Review to include a thorough review by two board members with a presentation and final voting of approval by the full board.
- Currently the VDSS IRB definition of expedited may be more comparable to a limited review, and an expedited review could adopt the procedures used by VDH.
- There may be additional advantage with a limited review that confidentiality is maintained.
- We should explore to understand whether the provision of Limited Review is most applicable to medical studies, and may not have as much utility for VDSS.

The conclusion of the VDSS IRB of the topic of Limited Review was to study further. A proposal to revise the definitions of VDSS IRB categories will be presented to the board at a later date.

FULL BOARD REVIEW

None this quarter

NEW BUSINESS

Review of Studies Approved in SFY 2019 to date:

Initial:

#2019-02 History of Sexual Abuse and Achievement of Permanency (Expedited)
#2019-03 Child Welfare Stipend Program Exit Survey (Exempt)
#2019-06 Council on Youth/VDSS DFS Youth Exit Survey (Exempt)
#2019-07 STREAMin3 Curriculum Pilot and Evaluation (Exempt)
#2019-09 VDSS Workload Measures Study (Exempt)
#2019-10 Child Welfare Workers' Attitudes, EB Practice, and Kinship Placement Decisions (Expedited)
#2019-11 Foster, Adoptive & Kinship Parent Survey (Exempt)
#2019-09 Virginia Workload Measures Study (Exempt)

Reliance Agreements:

Evidence-Based Services Statewide Survey

Continuing:

#2014-04 Wendy's Wonderful Kids Post-Adoption Study

#2016-06 Evaluation of SNAP Employment and Training Pilots

2018-02 The Longitudinal Infant and Family Environment (LIFE) Study

Modifications:

2018-06 PJAC Modifications 1, 2, 3 (Expedited)

2018-12 Linking Systems of Care Listening Tours Modifications 3, 4 (Exempt/Expedited)

Issues surrounding Reliance Agreements

So far in SFY2019 the VDSS has entered into one Reliance Agreement with the University of Richmond to study child welfare evidence based practices in Virginia. Two additional studies are near completion for Reliance Agreements: The Urban Institute for a study of how college students use available state benefits; and ICF to study approaches by caseworkers to screen and work with substance exposed infants. In each of these Reliance Agreements, a thorough review of the studies to be undertaken were reviewed by the VDSS IRB Chair before recommending agreement to VDSS leadership, i.e. Director of Research and Planning, Deputy Commissioner for Strategy and Engagement, and Commissioner Duke Storen.

For the two pending Agreements, the format was changed to include a brief summary of the study of concern. The chair will also send this new format to Board members for additional review and suggestions. Discussion of VDSS IRB Reliance Agreements included the following:

- Is the Reliance Agreement and MOA or an MOU?
- The Reliance Agreement is not defined specifically as either. While it can be considered a contract there are no costs involved and the requirements relate solely to the actions of the two IRB's involved.
- However, there may be a Data Sharing Agreement (DSA or MOA) that accompanies an IRB authorization agreement. This DSA is considered a contract and must be reviewed by VDSS General Services, as well as the data owner within VDSS (i.e. Family Services, Benefit Programs, Child Care and Early Childhood Develop, etc.). When PII is part of the data sharing/request, the IRB must review as either exempt, expedited, or full board review.
- For the past several years, VDSS has undertaken procedures to increase awareness and standardize the process of sharing data with other entities for research purposes. VDSS needs to know when data are shared, however there has been a great deal of confusion. Sometimes the request is for aggregated data, such as how many children were adopted in SFY2017. However, other data requests are more extensive and may include PII.
- There are new procedures now in place to track and monitor all data request to VDSS. While initially developed to track constituent communications with VDSS, the new CRM (Customer Response Management) system now includes constituent requests for data. While a request for a number or a brief aggregate does not need to be logged into the CRM, more in-depth or complex request will be logged and tracked.
- Components of the data request in the CRM includes questions such as "does it require PII", "does it require a DSA". Any requests for PII will need a DSA and IRB review. . Getting a better handle on what is being shared. Now all involved will be able to track. Moving in this direction and how we approach. More work is needed to educate and enhance awareness.

- What specifically are PII? For VDSS PII includes name, address, email, phone number, SSN, or a combination such as name and DOB. Client ID is not considered PII for VDSS.
- Criteria for Reliance Agreements generally include: a well regarded University, not an on-line University; large research institutions, must have an OHRP FWA number. If you have a Reliance Agreement does it still go through IRB review?
- Sometimes the VDSS IRB provides input to the study protocol, consents, etc. before we sign a Reliance Agreement.
- Related issue for further discussion is to define the VDSS IRB scope. At this time, we are required to review any study that involves as participants our clients or our employees. The study may or may not be one undertaken, sponsored, or requested by VDSS. Input from the AG's office would be helpful in this effort.

Criteria for IRB Review
The VDSS IRB currently lists the following criteria for VDSS IRB Review:

1. The necessity and utility of the research;
2. The adequacy of the description of potential benefits and risks involved and the appropriateness of the research methodology;
3. Risk level of the proposed research;
4. Whether the risks to the participants are outweighed by the potential benefits to them;
5. Whether the rights and welfare of the participants involved are adequately protected;
6. Whether voluntary informed consent is obtained by methods (including written consent form) that are adequate and appropriate considering the participants' educational level and language of greatest fluency;
7. Whether individuals proposing to supervise or conduct the research are competent and qualified; and
8. Whether the criteria for selection of participants are equitable.

In SFY2019, a study was submitted to the VDSS IRB that was ultimately denied for review. The chair had spent approximately seven months working with the PI to prepare an acceptable submission. The PI was a doctoral candidate from an on-line University. It become apparent that criteria 1, 2, 7 and 8 above were not met. This decision was confirmed three other IRB members, one of which was the program manager of the area of research.

It is important moving forward that these criteria be applied before a review of a study is begun by the IRB regardless of the type of approval procedure is applicable. Other thoughts by the board included:

- The chair will continue to consult with other IRB members if this concern arises again.
- A board member from another agency described their criteria as: necessity, utility, qualifications, and feasibility.

- It will also be helpful to revise the VDSS IRB website to provide greater clarification Items could include: is the study useful to VDSS, does VDSS have a legitimate interest in the research. Can VDSS commit resources to a study that has no utility?
- There should be evidence of support from the University if the research is for University requirements, e.g. dissertation, thesis, etc. In addition, a letter of support should be requested if other entities must provide resources towards the feasibility of the research.
- Members thought the VDSS IRB should review processes to make sure they are current, efficient, in compliance, etc. It would be helpful to look at other organizations to gain insight.

FUTURE MEETINGS

Members would like to meet quarterly. So far this calendar year we have met in February and April. The Chair suggested a meeting in September and another in early December. This seems agreeable to members present, and 11am to 1pm seems a good time. Suggestion to try for Tuesdays or Thursday. If a study is submitted that requires full board review, the chair will review first, then send to all member for review and a conference call will be used unless a previously scheduled meeting is within a reasonable time to include said review.

ADJOURNED TIME

The meeting adjourned at 2:00pm as planned.

ATTACHMENTS

As there were no studies for full board review, these minutes have no attachments.