ANNUAL REPORT ON HUMAN SUBJECTS RESEARCH

State Fiscal Year 2020

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 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 2020

Board Meetings

The VDSS IRB convened only once during the fiscal year, on October 22, 2019, due to guidance regarding COVID 19. Minutes of the meeting are provided in Appendix C of this report. In summary, the board had no studies submitted for full board review, and the meeting focused on

consolidating into one the various forms used by researchers to request IRB review. The board also reviewed studies submitted and approved to date in SFY 2020, and discussed potential enhancements to the IRB Policies, Procedures, and Website. Finally, the Chair apprised the IRB that minor edits, suggested by the Office of the Attorney General (OAG) to VDSS IRB regulatory documents, would be shared and discussed at a later date. These changes are scheduled to be submitted to the State Board of Social Services at a late date according to their meeting schedule.

Studies Approved

The VDSS IRB did not receive, review or approve any studies that required a full board review. Such studies pose more than minimum risk to participants and meet strict requirements for protection of human subjects such as informed consent, data security, confidentiality statements.

The IRB reviewed and approved six (6) 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 six studies approved under Expedited Review, four (4) submissions were for Initial Review, one for a Study Modification, and one for a Continuing Review. One study was approved by the VDSS IRB with an executed Inter-Agency Agreement (IAA, i.e. Reliance Agreement) between VDSS and the Principal Investigator's organization. This IAA provided the PI Organization to rely on the VDSS IRB for protection of human subjects.

The IRB determined two (2) 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.

CONCLUSION

All research approved by the IRB in SFY 2020 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. Fewer studies were submitted, reviewed, and approved by the VDSS IRB in SFY 2020, most likely due to the COVID-19 restrictions and guidelines,

Priorities for SFY 2021 remain:

- Submit changes to VDSS IRB regulations to the State Board of Social Services.
- 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, 2020;
- Streamlining procedures and forms;
- Increasing the awareness of protecting human subjects across the Commonwealth; and
- Updating the VDSS IRB website.

SFY 2020 ANNUAL REPORT ON HUMAN RESEARCH
VDSS INSTITUTIONAL REVIEW BOARD

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) 2020 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 2020, 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.

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.

ACTIVITIES SFY 2020

Board Meetings

The VDSS IRB convened only once during the fiscal year, on October 22, 2019, due to guidance regarding COVID 19. Minutes of the meeting are provided in Appendix C of this report. In

summary, the board had no studies submitted for full board review, and the meeting focused on consolidating into one the various forms used by researchers to request IRB review. The board also reviewed studies submitted and approved to date in SFY 2020, and discussed potential enhancements to the IRB Policies, Procedures, and Website. Finally, the Chair apprised the IRB that minor edits, suggested by the Office of the Attorney General (OAG) to VDSS IRB regulatory documents, would be shared and discussed at a later date. These changes are scheduled to be submitted to the State Board of Social Services at a late date according to their meeting schedule.

Studies Reviewed and Approved

Appendix A provides a detailed summary of all studies reviewed and approved by the VDSS IRB. The VDSS IRB did not receive, review or approve any studies that required a full board review. Such studies pose more than minimum risk to participants and meet strict requirements for protection of human subjects such as informed consent, data security, confidentiality statements.

The IRB reviewed and approved six (6) 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 six studies approved under Expedited Review, four (4) submissions were for Initial Review, one for a Study Modification, and one for a Continuing Review. One study was approved by the VDSS IRB with an executed Inter-Agency Agreement (IAA, i.e. Reliance Agreement) between VDSS and the Principal Investigator's organization. This IAA provided the PI Organization to rely on the VDSS IRB for protection of human subjects. Again, Appendix A provides a detailed summary of these six studies.

The IRB determined two (2) 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. Again, Appendix A provides a detailed summary of these two studies.

CONCLUSION

All research approved by the IRB in SFY 2020 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. Fewer studies were submitted, reviewed, and approved by the VDSS IRB in SFY 2020, most likely due to the COVID-19 restrictions and guidelines,

Priorities for SFY 2021 remain:

- Submit changes to VDSS IRB regulations to the State Board of Social Services.
- 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, 2020;
- Streamlining procedures and forms;
- Increasing the awareness of protecting human subjects across the Commonwealth; and
- Updating the VDSS IRB website.

APPENDIX A: REVIEW OF STUDIES BY VDSS IRB: SFY 2020

IRB #2014-05 Wendy's Wonderful Kids (WWK) Post Adoption Study	
Type of Submission	Continuing Review
Type of Review	Expedited
Agency Sponsor	Division of Family Services
Principal Investigator	Karin Main, MS
PI Affiliation	Child Trends
Submitted	9/12/2019
Approved	3/14/2014
Modification	9/8/2017
Approved	9/27/2019
Approval Ends	9/26/2020
Status	Continuing

Description: The VDSS IRB initially approved the Study on March 26, 2014, with subsequent Continuation Approvals each year. One modification to the initial study protocol was approved on September 8, 2017 to allow 18-year-olds to complete the follow-up interview a year earlier than originally proposed. This minimizes the risk of study attrition The study examines 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 placed in adoptive homes through the WWK program. Adoptees are invited to participate as they reach their 19th birthday. The study assesses their well-being and any challenges faced in young adulthood, including disruptions occurring during adoption.

The University of Wisconsin Survey Center, using in-person one-on-one interviews of approximately 1.5 hours either in the participant's home or in a neutral location, administers a survey. Interviews are audio recorded with the consent of the participant. Some of the interview questions assess risk behaviors and attitudes, including employment, physical health, sexual behavior, fertility and family formation, homelessness, mental health, delinquency, and victimization. Questions of a sensitive nature are asked and recorded through Audio CASI (computer-assisted self-interviewing), where the instrument is self-administered. The interviewer does not hear any of the participant's responses. Previous study indicates that the refusal rate when using this approach for answering sensitive questions < 1%. The local Department of Social Services establishes initial contact, recruits prospective survey participants, obtains permission for the research staff to contact the participant, and provides contact information provided by the Pl.

IRB #2018-06 Procedural Justice-Informed Alternatives to Contempt (PJAC)	
Type of Submission	Modification #4
Type of Review	Expedited
Agency Sponsor	Division of Child Support Enforcement
Funding (if applicable)	Federal Office of Child Support Enforcement (OCSE), ACF, US DHHS
Principal Investigator	Cindy Redcross, MS
PI Affiliation	MDRC
Initial Date Approved	6/18/2018
Modification date	9/2/2018; 10/30/2018; 3/5/2019
Date Submitted	4/7/2020
Date Approved	5/21/2020
Date Approval Ends	5/20/2021
Status	Continuing

Description: On 6/18/2018 the IRB approved the first phase of the Study, i.e. randomization and enrollment of participants with data from child support agency records, program participation data, administrative court and jail data (if available), and employment and earnings data from the National Directory of New Hires. Security measures are taken to protect and restrict access to these data, as described in the Data Sharing Agreement between VDSS and MDRC of 5/31/2018. On 8/2/2018 the IRB approved the first study modification, approving visits and staff interviews to gather background information, assess early operations, and observe public court proceedings. On 10/302018 the IRB approved a second modification, providing for a pretest of the participant survey instrument. On 3/19/2019 the IRB approved a third study modification to include implementation of site visits: observations of public court proceedings; interviews of child support case workers, managers, agency legal staff, and management staff at referral partner organizations; and case file reviews. Researchers obtain verbal consent from study participants, and staff names are not linked to any interview responses. Confidentiality agreements in Modification #1 remain in effect.

MDRC submitted their most recent (fourth) Request for Modification to the Study to the VDSS IRB on 4/7/20202 to implement a child support case worker survey online using Qualtrics. MDRC submitted a copy of the survey questions, recruitment procedures, and consent procedures. Twelve DCSE caseworkers in two field offices will be invited to complete the survey. Consent information is contained in the email invitation as well as on the first page of the survey. Participants will be asked to document their consent by answering a question at the end of the consent page. Although staff names and email addresses are stored in Qualtrics for sending the survey link electronically, the survey responses will not be linked to other study data. Confidentiality agreements signed for Modification #1 continue to remain in effect.

IRB 2020-05 (formerly #2019-01) Behavioral Encouragement Increase EITC Uptake	
Type of Submission	Initial
Type of Review	Expedited
Agency Sponsor	VDSS Office of Innovation and Strategic Initiatives (OISI)
Funding	Abdul Latif Jameel Poverty Action Lab (J-PAL), North America | MIT
Principal Investigator	Massey Whorley, MPP
PI Affiliation	VDSS, OISI
Date Submitted	10/21/2019
Date Approved	12/18/2019
Modification Submitted	1/13/2019
Modification Approved	1/18/2019
Date Approval Ends	1/13/2021
Status	Continuing

Description: This research study was initially proposed in SFY 2019 by lead IRS researcher Dr. Dayanand Manoli of the University of Texas Austin. The procedures for the study however, were not feasible until SFY 2020. The purpose of the study is to test the effectiveness of different methods of outreach and communication to Virginia citizens that may motivate them to file a tax return and claim the Earned Income Tax Credit (EITC). The study included two distinct phases, one phase for the outreach intervention and a second phase to study outcomes of the intervention. While the initial draft Data Sharing Agreement (DSA) for the study was reviewed and approved by the IRB, subsequent changes to this document required the IRB to approve only the first, intervention phase.

A study modification formally separating the project, and requesting review of the outreach intervention phase only, was reviewed and approved by the IRB on 1/18/2019. This approval focused solely on the outreach messaging intervention, to consist of random assignment of participants to five research groups (four text treatment groups and one control group). Outreach to participants will vary by treatment group. The study will be implemented solely by staff at VDSS with no data sharing outside of VDSS required. A subsequent IRB Modification is planned for submission later, and will include a final executed DSA and a detailed Protocol of procedures. Specifically, the Protocol will describe matching participant outreach method(s) to tax records. Based on which communication methods are most effective, VDSS intends to improve outreach strategies and plans.

IRB #2020-01 Virginia Early Childhood Foundation (VECF) Evaluation and Policy Analysis: Smart Beginnings Systems- and Capacity-Building Outcomes	
Type of Submission	Initial
Type of Review	Expedited
Agency Sponsor	VDSS Child Care and Early Childhood Development (CCECD)
Funding	VECF via award from US DHHS and US DOE
Principal Investigator	Todd Grindal, ED.D
PI Affiliation	SRI Education, Center for Learning and Development
Submitted	7/19/2019
Approved	9/12/2019
IAA Approved	10/7/2019
Approval Ends	12/31/2020
Status	Continuing

Description: The purpose of this project is to provide VECF with information to support its work with the Smart Beginnings (SB) network. The project includes three activities: 1) develop a strategy map that identifies the key components of the SB initiative and metrics for tracking success; 2) conduct a survey of 18 SB directors about their implementation of current activities; and 3) conduct a case study of 8 SB communities to learn about local priorities, successes, and challenges. Survey and case study findings will inform revisions to the strategy map and indicators. Findings will be disseminated via a legislative brief and policy paper.

Funding for the research is provided through a contract with VECF as part of a federal award from the US Department of Health and Human Services, and the US Department of Education.

The VDSS Division of Child Care and Early Childhood Development is collaborating with VECF for the Smart Beginnings Initiative. In December, an Inter-Agency Agreement was executed between VDSS and SRI allowing SRI and VECF to rely on the VDSS IRB for all protections required for human subject research.

IRB #2020-02 Correlation between Secondary Traumatic Stress, Burnout, and Employee Satisfaction and Employee Engagement amongst Residential Facility Employees in Children's Residential Facilities	
Type of Submission	Initial
Type of Review	Expedited
Agency Sponsor	VDSS Office of Research and Planning
Principal Investigator	Tiffani White-Symeonides, MEd, MA
PI Affiliation	Doctoral Candidate, Grand Canyon University,
Submitted	7/2//2019
Approved	9/24/2019
Modification Submitted	12/31/2019
Modification Approved	1/6/2020
Approval Ends	1/6/2021
Status	Continuing

Description of Initial Submission: The purpose of the study is to explore the dynamics and motivations of staff working in Virginia child residential facilities. The principal investigator is conducting a quantitative correlational study utilizing four ordinal variables derived from standardized scaled surveys from the literature. Via email, the facility directors will distribute the following study information to eligible employee: study purpose, recruitment letter, anonymous informed consent letter, confidentiality, contact information for questions, and survey links. Surveys include: ProQOL5 (Stamm, 2010); Decision Wise Leadership Intelligence, Employee Satisfaction and Engagement Survey (Decision Wise, LLC, 2016); and a demographic questionnaire describing basic information about study participants. At no time will the program directors know or be informed as to the employees who did or did not complete the surveys. All responses are anonymous and no personal identifying information will be available to the researcher, program directors, or relevant faculty of the researcher. In addition, the principal investigator will not report any categories or groups of less than five responses.

In December 2019, the Principal Investigator (PI) submitted a modification request to the VDSS IRB with the following changes: the Decision Wise Leadership Intelligence, Employee Satisfaction and Engagement Survey (deemed no longer appropriate) was replaced by the Work & Well-Being Survey (UWES-9) (Schaufel & Bakker, 2003), and the Job Satisfaction Survey (Spector, 1994). As in the approved protocol, surveys will be administered online via SurveyMonkey. The PRO-QOL 5 and demographic questionnaire remains the same, except that certain questions are provided categorical response choices as opposed to open-ended text. Finally, the Informed Consent document was changed to reflect a new time frame for the study.

IRB #2020-04 Credit Check Program Evaluation	
Type of Submission	Initial
Type of Review	Expedited
Agency Sponsor	Division of Family Services
Principal Investigator	John Gyourko, MSW Candidate
PI Affiliation	VCU School of Social Work
Submitted	7/29/2019
Approved	10/31/2019
Modification	None
Date Approval Ends	10/1/2020
Status	Continuing

Description: The proposed study will use credit check program records managed by the Division of Family Services as a secondary dataset for analysis. Data for the study, which have already been compiled and de-identified during the course of regular VDSS credit check program activities, include affected youths' credit report issue details, sociodemographic characteristics, and foster care placement data. The current study seeks only to analyze this secondary dataset and will not actively collect any additional data. The study will use statistical tests, including Chi-Square and nonparametric Kruskal-Wallis and Mann-Whitney U tests, to explore relationships between sociodemographic variables (age, race, gender, and disability diagnosis of affected youth), foster care case history details (general foster care placement history and sex trafficking victim status), and discovered credit report issues.

The VDSS Division of Family Services has approved the data request for the de-identified dataset for this study, and will provide these data to the PI.

Child Welfare Expert Consensus Through Virtual Reality Learning	
Type of Submission	Initial
Type of Review	Exempt (45 CFR 46.101(b) (1)
Agency Sponsor	Division of Family Services
Funding	Utah Division of Child & Family Services (DCFS)
Principal Investigator	Chad McDonald, MS Social Work
PI Affiliation	College of Social Work, University of Utah
Submitted	9/20/2019
Approved	9/24/2019
Modification	None
Date Approval Ends	NA for Exempt Studies
Status	Continuing

Description: The purpose of this demonstration study is to develop standard measures for risk assessment, from child welfare experts, for the potential use in scoring a virtual reality-learning tool. Possible expert participants include trainers, supervisors, coaches, mentors, and other workers who consistently meet/exceed performance in assessing risks. The study will inform child welfare agencies and other relevant researchers in the field on any effect the virtual reality tool may have in developing common social work skills. Data from the study will provide feedback to new or less experienced workers regarding their skill level, compared to experts from the research demonstration. The investigators may use the results in reports, academic articles, and conference presentations.

Participants will use a virtual reality headset or standard PC to assess two separate child welfare concerns. The assessment will take approximately one-hour to complete, and may be taken at a time and place convenient to participants. A demographics survey questionnaire will immediately follow completion of the assessments. Participation in the research study is voluntary. Refusal to participate, or discontinuing participation, will involve no penalty/loss of benefits to the participants, nor affect employment status in any way. All records that identify individuals are kept private, and records kept in locked filing cabinets, password protected computers, and/or encrypted databases. Only those working in the study at the Social Research Institute will be allowed access to participant information. Although the results may be published or included in reports, no information that could identify participants will be included. The VDSS Division of Family Services will assistance the PI in identifying individuals for participation in the study, however only those who work with this study at the Social Research Institute will be allowed access to participant responses.

IRB #2020-08 Family Services Workforce Survey	
Type of Submission	Initial
Type of Review	Exempt (45 CFR 46.101(b)(5)
Agency Sponsor	Division of Family Services
Principal Investigator	Em Parente, LCSW, PhD
PI Affiliation	VDSS Division of Family Services
Submitted	4/2/2020
Approved	4/10/2020
Modification	None
Date Approval Ends	NA for Exempt Studies
Status	Continuing

Description: The purpose of this survey is to gather information from the Family Services workforce about VDSS communication efforts, the accessibility and effectiveness of services within the community, agency responses to secondary trauma, and agencies work to solicit feedback from parents or caregivers. We hope to gather this information to aid in best-practice efforts throughout the Commonwealth of Virginia as well as to include as evidence of our ongoing incorporation of stakeholder feedback in our Annual report to the Children's Bureau regarding efforts to improve outcomes in the child welfare system in Virginia (APSR).

A Survey Monkey survey link will be provided to Family Service Specialists via email. Participation in this survey is voluntary. Responses will be anonymous. Participants may decline to participate or withdraw from the survey at any time. The study does not collect any personally identifiable information at any point.

The Virginia Department of Social Services (VDSS) may share the aggregate data with the local departments of social services, community partners, stakeholders, and the Children's Bureau. Additionally, two Virginia Commonwealth University (VCU) MSW students will collect the data and analyze portions of the survey for a student research paper. This paper will not be published. To prevent possible identification of participants and their responses, any shared aggregate data or analysis will exclude any category where less than five participants responded. There is no anticipated risk or tangible benefit to study participants. However, participants may benefit from the knowledge that they are contributing to in the program evaluation. The entire study will be managed and implemented by VDSS Division of Family Services

STUDIES APPROVED BY FULL BOARD REVIEW

The VDSS IRB did not receive, nor did they approve, any studies in SFY 2020 requiring full board review.

STUDIES APPROVED BY RELIANCE AGREEMENT

The VDSS IRB did not receive, nor did they approve, any studies in SFY 2020 requiring a Reliance Agreement, i.e. Inter-Agency Agreement (IAA).

STUDIES COMPLETED

IRB #2018-01: Measurement of racial and other disparities in the child welfare caseload of the Charlottesville Department of Social Services.

On 10/23/2017, the VDSS IRB approved by Exempt Procedures (45 CFR 46.101(b)(5) the study IRB #2018-01: Measurement of racial and other disparities in the child welfare caseload of the Charlottesville Department of Social Services. Michele Claibourn, PhD, Director of the Public Interest Data Lab at the University of Virginia (UVA) served as Principal Investigator (PI) for the research. Data from the VDSS OASIS system was provided through a data sharing agreement between the Charlottesville Department of Social Services and the UVA Lab, executed 10/23/2017. VDSS Office of Research and Planning provided de-identified data for children with maltreatment reported to the Charlottesville DSS who subsequently entered foster care, and who may have also exited foster care. Data included characteristics of these children such as date of birth, gender, race, ethnicity, type of maltreatment, and date of entry to foster care.

A final report of the study was provided to the VDSS IRB and published by the UVA Public Interest Data Lab. Both the Executive Summary and full study details are available at the following:

https://www.charlottesville.gov/DocumentCenter/View/818/2019-Foster-Care-Study-PDF

APPENDIX B: VDSS IRB MEMBERSHIP FOR SFY 2020

VDSS INSTITUTIONAL REVIEW BOARD MEMBER ROSTER SFY 2020			
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 Information Systems (Business Analyst)
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: VDSS IRB MINUTES OCTOBER 22, 2019

DATE: **October 22, 2019**

TIME: **11:00 am to 1:00 pm**

LOCATION: **801 E. Main Street, 6th Floor Conference Room**

MEMBERS PRESENT: Eleanor Brown, Gail Jennings, Carolyn Hawley, Mary Disse, Traci Wike, Jeff Price, Em Parente (checked in at 11:35). Absent: Erika Jones-Haskins, Dhara Amin, Hailey Cleary, 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

Common Rule
It 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. 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

Reliance Agreements
Need 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.

It will also be helpful to revise the VDSS IRB website to provide greater clarification. Items could include: is the study useful to VDSS, or does VDSS have a legitimate interest in the research? Can VDSS commit resources to a study that has no utility? Is the study feasible? Is the researcher qualified?

Criteria for IRB Review
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.

VDSS IRB Report to General Assembly Fall 2019
Shared with IRB August 2019

FULL BOARD REVIEW

CHADIS study – PI submitted responses to the VDSS IRB questions. They are waiting on IRB Approval for the study from Johns Hopkins. Once this is completed, VDSS will review again.

VDSS IRB is waiting on final review by the Johns Hopkins. The IRB chair decided not to rely on Johns Hopkins for a review of the part involving VDSS. The project will require a data sharing agreement.

REPORT OF OTHER REVIEWS AND APPROVALS (SFY 2020 TO DATE)

Approved
2014-04 WWK Post Adoption - Continuing Review
2016-02 Fairfax County LDSS Customer Satisfaction Survey – determined not research
2019-08 LSC Evaluation - Modification
2019-18 Pre-school Development Grant with VDSS, VDOE, UVA - Exempt
2019-20 VA Infant Toddler Support Network and Infant Toddler Mental Health – Expedited Gail Jennings
2020-02 Grand Canyon University Doctoral Student – Expedited Gail Jennings
2020-03 VDSS Family Services Training Simulation study - Exempt
2020-01 Reliance Agreement with VDSS, VECF, SRI for Smart Beginnings Evaluation – Expedited Traci Wike (SRI will rely on the VDSS IRB for review of the study)

In Process
2019-05 CHADIS
2019-07 QIC-WD Reliance Agreement review (VDSS IRB is relying on the University of Louisville; Chair requested copies of QIC-WD IRB submissions, reviews and approvals that the U of L IRB possesses; study is more complex because VDSS has a data sharing agreement with the University of Nebraska-Lincoln and the University of Colorado-Denver. The VDSS IRB had some initial concerns about the scope of the data request to VDSS from the partner agencies.)
2020-04 VCU student and VDSS employee study of foster youth and credit reports
2020-05 VDSS CVS study of EITC

NEW BUSINESS

Proposed Meeting dates for CY 2020: Chair will send a Doodle Poll re: availability for dates in each quarter through October 2020. Recommend a minimum of three meetings to be held in the fiscal year.

- Tuesday, January 21, 2020
- Thursday, April 16, 2020
- Tuesday, September 14, 2020

Review of revisions to Submission Form (collapsing into one):

- Propose to develop one form that applies to all studies (exempt, expedited and full).
- The previous version was a Word form where users can only insert in fillable spaces. The members agreed this was a reasonable approach to the form, and the users should save the form as a PDF file and share electronically.
- The new version includes initial questions to disqualify for submission any proposals that do not involve human subjects' research, as well as the ability for the researcher to check any applicable

exemption category. The IRB however, makes the final determination of whether or not the study is exempt.

- The PI must continue to submit the full protocol, consent form, and other related documents.
- The chair/coordinators should determine if the form conforms to new regulations under the Final Rule.
- Chair recognizes that the PI does not always provide the required attachments and the protocol may not provide sufficient detail.
- Members discussed where the instruction to submit a full protocol should be inserted in the form. Decided to add instruction in the section "Protocol Abstract", as well as the list of documents to be submitted with the Initial Request.
- Board agreed to put the list of required attachments before the PI signature line.
- Suggestions also included - add a version number and date, use Track changes for any new edits, and require an IRB stamp on the final approved version of the consent form and the protocol. The IRB approval notice could also include as attachments each final approved document with the IRB approval stamp.
- In the discussion for student-led projects, suggestions included requiring contact information on the advisor or instructor if a student is conducting the study. Perhaps require a signature from the advisor/instructor if it is a student-led research project.
- The Board also suggested adding a section "Population" that includes existing information about the study population and adding language about vulnerable populations.

VDSS IRB Policies and Manual: Reference guidance and regulations are located in many places (e.g., web site, written manual, topic-specific guidance documents). Goal is to streamline and co-locate in one place. If there is a new topic, supplement the manual. Investigate other forms of technical assistance (e.g., FAQs).

VDSS IRB Website: Need to do more education and outreach to the LDSS re: the role of the IRB and its function in reviewing research. Supplement with information posted to FUSION.

Reliance Agreements:
The VDSS IRB wants to improve its process for relying on another IRB and ensure that the VDSS IRB is fully informed of any reviews conducted by the reviewing IRB through more sharing of documents. The Reliance Agreement contract template has been modified to include more details about the involved study, and other modifications may be added in the near future.

Other: Reviewed studies submitted in SFY 2020, both those approved and currently under review. The chair also noted the completion of the annual IRB report to the GA in Fall 2019, which was sent to board members in September.

Informed the IRB that VDSS has several new deputy Commissioners, including Dr. Hari Dulal, to whom the Office of Research and Planning reports. Dr. Dulal's goal is to have ORP complete more research

studies. This increases the opportunities for more reviews for the IRB. The Chair proposes that when the board conducts expedited reviews of VDSS led studies, that reviews be conducted by two external IRB members to avoid any conflict of interest.

Asked a question as to whether the IRB requests a final report from investigators once the study is complete, the chair indicates that the IRB does require a final copy of findings studies that received expedited and full board reviews. The IRB strongly encourages exempt studies to submit results.

The Board also discussed the obligation of the IRB to review the soundness of method and design of the study. There was general agreement that the IRB could not approve a study that would not, in the informed opinion of the reviewers, yield valid, reliable research. The IRB is not however, required to provide guidance such as would be appropriate of an employee supervisor or faculty mentor. The reviewer(s) have the discretion to make suggestions or require re-writes but not to make them.

ADJOURNED TIME: 1:23 PM

ATTACHMENT

VDSS IRB REVIEW CHECKLIST SUMMER 2019

ATTACHMENT: VDSS IRB REVIEW CHECKLIST SUMMER 2019

PI Name:	
Study Title:	
VDSS IRB Study #	
IRB Reviewer Name:	
Date reviewed:	

EXPEDITED REVIEW OF RESEARCH

Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the expedited categories, may be reviewed by the IRB through the expedited review procedure. The activities listed should not be deemed to be of minimal risk simply because they are included on the list. Inclusion on the list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

Minimal Risk: Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

EXPEDITED REVIEW CRITERIA – STUDY MUST MEET EACH OF THE FOLLOWING CRITERIA:

	The research is no more than minimal risk.
	The research is not classified (US national security purposes only).
	The subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing.
	If #3 is not met, reasonable and appropriate protections must be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal?

CATEGORIES THAT ARE ELIGIBLE FOR EXPEDITED REVIEW – NOTE ANY/ALL THAT APPLY

	1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
	(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
	(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling. NOTE: VDSS does not participate in clinical studies.
	2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
	a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an eight week period and collection may not occur more frequently than twice weekly; or
	b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the of 50 ml or 3 ml per kg in an eight week period and collection may not occur more frequently than twice weekly.
	3. Prospective collection of biological specimens for research purposes by noninvasive means
	4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation)

	routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
	5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
	6. Collection of data from voice, video, digital, or image recordings made for research purposes
	7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
	8. Continuing review of research previously approved by the convened IRB where:
	a) the research is permanently closed to the enrollment of new subjects;
	b) all subjects have completed all research-related interventions; and
	c) the research remains active only for long-term follow-up of subjects; or, where no subjects have been enrolled and no additional risks have been identified; or, here the remaining research activities are limited to data analysis.
	9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

FUNDING - If any funding from the following, see Guidance for additional requirements.

	U.S. Department of Justice (DOJ) including the National Institute of Justice
	U.S. Department of Education (DOE)
	National Institute on Disability and Rehabilitation Research (NIDRR)

DETERMINATION - Based on information in the protocol, I have made the following determination(s):

	The activity is not eligible for expedited review and must be reviewed by the full IRB
	The activity is eligible for expedited review but should be reviewed by the full IRB (include reason here).
	The activity is appropriate for expedited review and the review category is checked in the prior section.

ASSESSMENT OF PROTOCOL - Is the proposed research scientifically sound?

	Protocol lays out a research proposal which is scientifically sound or has scholarly merit?
	Research is likely to answer its proposed research question or hypothesis?
	Available background information supports the appropriateness and adequacy of proposed research?
	Sample size and population is appropriate for the proposed research?
	Adequate time, resources, staffing, etc. exist for safe and appropriate conduct of this research?
	Will the research design yield useful data?
	Other observations about scientific soundness of the protocol?

ASSESSMENT OF SUBJECT POPULATION/RECRUITMENT

	Is enrollment of subjects equitable?

	Is the subject population appropriate for the research?
	Are there any vulnerable populations?
	If applicable, are appropriate safeguards in place for vulnerable populations?
	Is recruitment non-coercive and consistent with all regulations, laws and VDSS guidance documents?

ASSESSMENT OF RISK

	Is this research more than minimal risk?
	Are subjects being subjected to unnecessary risks?

MINIMIZATION OF RISK

	Are adequate provisions in place to minimize research risks? (Examples include frequent monitoring, qualified personnel, response to emergency situations)
	Does monitoring include a data safety monitoring board? If appropriate
	Should this research be periodically reviewed more frequently than once per year?

ASSESSMENT OF ANTICIPATED BENEFITS

	Is there direct benefit to the subject?
	Does research provide therapeutic benefit?
	Does this research primarily benefit society (involves procedures performed for research purposes only without direct benefit to subject)
	Is compensation offered to subject?
	Do the benefits of this research outweigh the risks?

INFORMED CONSENT 45 CFR 46.101(B)(5)

	Is the consent form is written in language likely to be understandable to the subject population?
	Will the potential subject be approached for informed consent in an appropriate manner (i.e. investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. 45 CFR 46.116)
	Is compensation offered to subject?
	Do the benefits of this research outweigh the risks?

DOES THE INFORMED CONSENT DOCUMENT/PROCEDURE INCLUDE THE EIGHT REQUIRED ELEMENTS

	1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental
	2. A description of any reasonably foreseeable risks or discomforts to the subject
	3. A description of any benefits to the subject or to others which may reasonably be expected from the research
	4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
	5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
	6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained

	7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
	8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled

PRIVACY/CONFIDENTIALITY/DATA SECURITY

	Will the PI. collect sensitive information about the subject?
	Are adequate provisions in place to protect privacy/confidentiality?
	Will participation be documented in subject's VDSS case record (including a copy of the consent/assent form(s)?
	Is security related to electronic data adequately addressed?

OTHER CONSIDERATIONS

	When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects. (45 CFR 46.111(b))
	Is there any conflict of interest for the PI or other study personnel?
	If this research is related to a grant or contract, is the information in the grant or contract appropriate and consistent with the research documents submitted to the IRB?

If needed, please provide a narrative summary of any changes/modifications required.

I recommend:

	Approval
	Modifications required (see my comments above)
	Defer: