

ANNUAL REPORT ON HUMAN SUBJECTS RESEARCH

State Fiscal Year 2021

**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 2021

Board Meetings

The VDSS IRB did not convene during SFY2021 due to 1) the COVID-19 pandemic; and 2) the limited number of research studies submitted for review.

Studies Approved

Studies submitted to the VDSS IRB in SFY2021 are described with more detail in Attachment A and summarized briefly here:

- The VDSS IRB did not receive, review or approve any studies requiring full board review, as no studies submitted posed more than minimum risk to participants under 22VAC40-890 and 45CFR46.

- The IRB reviewed and approved one initial research project and three modifications to existing research projects, under Expedited Review Procedures described in 22VAC40-890 and 45CFR46. While these procedures include a review of all elements required of a full Board Review, only one-to-two IRB members are required to conduct the review.
- Two research projects were deemed Exempt from IRB Review, under conditions described in 22VAC40-890 and 45CFR46.

CONCLUSION

All research approved by the IRB in SFY 2021 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. As in SFY2020, few studies were submitted, reviewed, and approved by the VDSS IRB in SFY 2021, again due to the COVID-19 restrictions and guidelines.

Priorities for SFY 2022 include:

- Submit to the Virginia Board of Social Services for approval, revisions to IRB regulations in 22VAC40-890. These revisions will provide compliance with the federal Revised Common Rule 45 CFR 46 that became effective January 1, 2020. Said revisions provide additional clarity and appropriate lenience in human subject research reviews.
- Promote use of the Collaborative Institutional Training Initiative (CITI) among VDSS and LDSS staff who are involved in leadership or departmental research, as well as new and continuing IRB members
- Streamline VDSS IRB procedures and forms, including updates to the VDSS IRB website;
- Increase awareness of protecting human subjects across the Commonwealth, especially as projects using the new survey tool Qualtrics could require IRB review and approval.

**FY 2021 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) 2021 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, equitable

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 September 5, 2023 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 serves 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.

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 2021

Board Meetings

The VDSS IRB did not convene during SFY2021 due to the COV19 pandemic and the limited number of research studies submitted for review.

Studies Approved

Studies submitted to the VDSS IRB in SFY2021 are described with more detail in Attachment A.

- 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 must meet strict requirements for protection of human subjects such as informed consent, data security, confidentiality statements;
- The IRB reviewed and approved four modifications to existing research projects, under Expedited Review Procedures described in 45 CFR 46, and one initial request also reviewed under Expedited Review Procedures. While these procedures require all requirements of a full Board Review be considered, only one-to-two IRB members are required to conduct the review;
- Two research projects were deemed Exempt from IRB Review, under conditions described in 45 CFR 46

CONCLUSION

All research approved by the IRB in SFY 2021 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. As in SFY2020, few studies were submitted, reviewed, and approved by the VDSS IRB in SFY 2021, again due to the COVID-19 restrictions and guidelines.

Priorities for SFY 2022 remain:

- Submit to the Virginia Board of Social Services for approval, revisions to IRB regulations in 22VAC40-890. These revisions will provide compliance with the federal Revised Common Rule 45 CFR 46 that became effective January 1, 2020. Said revisions provide additional clarity and appropriate lenience in human subject research reviews.
- Promote use of the Collaborative Institutional Training Initiative (CITI) among VDSS and LDSS staff who are involved in leadership or departmental research, as well as new and continuing IRB members
- Streamline VDSS IRB procedures and forms, including updates to the VDSS IRB website;
- Increase awareness of protecting human subjects across the Commonwealth, especially as projects using the new survey tool Qualtrics could require IRB review and approval.

APPENDIX A: REVIEW OF STUDIES BY VDSS IRB: SFY 2021

STUDIES APPROVED BY EXPEDITED REVIEW PROCEDURES

| IRB #2018-06 Procedural Justice-Informed Alternatives to Contempt (PJAC) | |
|--|--|
| Type of Submission | Modification #5 |
| Type of Review | Expedited under 45 CFR 46 |
| Agency Sponsor | Division of Child Support Enforcement |
| Funding (if applicable) | Office of Child Support Enforcement (OCSE), ACF, US DHHS |
| Principal Investigator | Cindy Redcross, MS |
| PI Affiliation | MDRC |
| Approved | Initial Approval 6/18/2018 |
| Modification | 9/2/2018; 10/30/2018; 3/5/2019; 5/21/2020; 9/1/2020 |
| Date Approval Ends | Continuing |
| Status | Continuing |
| <p>On June 18, 2018 the VDSS IRB approved the first phase of IRB #2018-06 to involve randomization and enrollment with data to include 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 described in the Data Sharing Agreement between VDSS and MDRC of 5/31/2018.</p> <p>On August 2, 2018, the VDSS IRB approved the first modification to the Study, providing for visits and staff interviews to gather background information, assess early operations, and observe public court proceedings. On October 30, 2018, the VDSS IRB approved a second modification to IRB #2018-06, providing for a pretest of the participant survey instrument.</p> <p>On March 5, 2019, the VDSS IRB approved a third modification to IRB #2018-06 providing for implementation of site visits. On May 21, 2020, the VDSS IRB approved a fourth modification to IRB #2018-06, providing for implementation of a child support case worker survey, administered online through Qualtrics. On September 1, 2020, the VDSS IRB approved a fifth modification to IRB #2018-06 providing for a second round of virtual site visits. New questions relative to COVID-19 are included in this second round of virtual visits. For this second round, the verbal consent approach previously approved is expected.</p> | |

| IRB #2018-06 Procedural Justice-Informed Alternatives to Contempt (PJAC) | |
|--|--|
| Type of Submission | Modification #6 |
| Type of Review | Expedited under 45 CFR 46 |
| Agency Sponsor | Division of Child Support Enforcement |
| Funding (if applicable) | Office of Child Support Enforcement (OCSE), ACF, US DHHS |
| Principal Investigator | Cindy Redcross, MS |
| PI Affiliation | MDRC |
| Approved | 6/18/2018 |
| Modification | 9/2/2018; 10/30/2018; 3/5/2019; 5/21/2020; 9/1/2020; 9/23/2020 |
| Date Approval Ends | Continuing |
| Status | Continuing |
| <p>Description: On August 2, 2018, the VDSS IRB approved the first modification to the Study, providing for visits and staff interviews to gather background information, assess early operations, and observe public court proceedings. On October 30, 2018, the VDSS IRB approved a second modification to IRB #2018-06, providing for a pretest of the participant survey instrument. On March 5, 2019, the VDSS IRB approved a third modification to IRB #2018-06 providing for implementation of site visits. On May 21, 2020, the VDSS IRB approved a fourth modification to IRB #2018-06, providing for implementation of a child support case worker survey, administered online through Qualtrics. On September 20, 2020, the VDSS IRB approved a fifth modification to IRB #2018-06 providing for a second round of virtual site visits. New questions relative to COVID-19 are included in this second round of virtual visits. For this second round, the verbal consent approach previously approved is expected.</p> <p>On September 23, 2020 the VDSS IRB approved a sixth request for modification to IRB #2018-06. The requested modification involved revisions to previous study procedures, recruitment strategy/materials and Consent/Assent. In this modification, the researchers will add a staff time study and its accompanying recruitment and consent procedures to the approved data collection instruments for the PJAC Demonstration. Up to 15 case managers serving participants in the PJAC treatment and control groups will be fielded the time study, which will require respondents to allocate the time they spend each day across several pre-specified categories for a two-week period. Case managers will be invited to take the staff time study via email. The time study will be administered in Qualtrics. Case managers will be presented with the informed consent at the start of the time study and be required to document their consent before proceeding by checking a box.</p> | |

IRB # 2020-02 The Correlation between Secondary Traumatic Stress, Burnout and Employee Satisfaction and Employee Engagement Amongst Residential Facility Employees in Children's Residential Facilities

| | |
|------------------------|---------------------------------|
| Type of Submission | Modification #3 |
| Type of Review | Expedited under 45 CFR 46 |
| Agency Sponsor | Grand Canyon University |
| Principal Investigator | Tiffany Symeonides |
| PI Affiliation | Doctoral Student |
| Submitted | September 12, 2019 |
| Approved | September 24, 2019 |
| Modification | 1/6/2020; 4/28/2020; 10/14/2020 |
| Approval Ends | Continuing |
| Status | Continuing |

Description: The initial study was approved by the VDSS IRB 9/24/2019. The purpose of the research was to measure secondary traumatic stress, burnout and employee satisfaction as these characteristics relate to employee engagement among Virginia residential facility employees. A modification to the study, to use more appropriate and reliable instruments to measure these concepts was approved by the VDSS IRB on 1/6/2020. Due to the low response rate from the Virginia population, a second modification to the study was approved by the VDSS IRB on April 28 2020. This modification expanded the research beyond Virginia into other areas of the Southeastern United States.

On 10/14/2020 the IRB approved a modification to include social media platforms to distribute the Recruitment Script and the survey link to the following private, Facebook Groups: Doctorz in the Making, #DoctoralMomLife, Quantitative Studies Group; Dissertation E-Collaborative Group and Residential Care Facilities Alliance. The principal investigator has contacted each Facebook Group Administrator and received approval via message on Facebook Messenger to inquire about the process of obtaining for research recruitment and distributing survey materials amongst members of the Facebook group. In addition, there are three groups that are moderated by Grand Canyon University alumni/faculty members: Doctorz in the Making, Quantitative Studies Group, and Dissertation ECollaborative Group. All approved text for consent, the survey, and recruitment materials remain as approved previously.

| IRB # 2020-05 Behavior Encouragement: Increase EITC Uptake | |
|--|--|
| Type of Submission | Modification #2 |
| Type of Review | Expedited under 45 CFR 46 |
| Agency Sponsor | VDSS |
| Principal Investigator | Jeff Price |
| PI Affiliation | Director, VDSS Office of Research and Planning |
| Submitted | 9/26/2019 |
| Approved | 10/23/2019 |
| Modification | 1/14/2020; 9/3/2020 |
| Approval Ends | Continuing |
| Status | Continuing |
| <p>Description: The VDSS IRB approved IRB #2020-05, Behavior Encouragement: Increase EITC Uptake, on October 23, 2019. The proposed study intended to conduct a randomized control trial testing the effectiveness of different methods of communication to motivate people to file a tax return and claim the Earned Income Tax Credit (EITC).</p> <p>On January 14, 2020, the IRB approved a modification to the original study protocol, dividing the research into two phases. Phase 1 will consist of randomly assigning participants to five research groups (four text treatment groups and one control group) and will be implemented solely by staff at VDSS with no data sharing outside of VDSS required.</p> <p>A second modification to IRB #2020-05 was approved by the IRB on September 3, 2020. The purpose of this modification was aligned with the initial purpose of the EITC uptake research, to allow additional outreach to study randomized group of Virginia citizens enrolled in SNAP, TANF, and/or Medicaid to determine their application for EIP stimulus benefits.</p> | |

| IRB # 2021-01 VDSS LGBTQ+ Training Evaluation | |
|--|--|
| Type of Submission | Initial Review |
| Type of Review | Expedited under Title 45 CFR 46 |
| Agency Sponsor | Virginia Commonwealth University; Virginia DSS |
| Principal Investigator | John Ruane; Mikaela Doench |
| PI Affiliation | MSW Candidates |
| Submitted | 12/8/2020 |
| Approved | 1/5/2021 |
| Modification | None submitted |
| Approval Ends | 1/5/2022 |
| Status | In progress |
| <p>Description: The purpose of the research is to understand perspectives of child welfare workers employed by the local departments of social services as well as the resource parents approved by the VDSS to serve foster care children. The study aims to have approximately 100 respondents from various local child welfare workers across the state and approximately 25 respondents from local resource parents across the state.</p> <p>The study intends to utilize an online survey powered to collect data from respondents. Both research questions have their own set of surveys, each with six questions that are comprised of some multiple-choice validation questions, two Likert scale questions, and one short answer question. No PII will be included in the survey or survey responses. The two PIs will analyze both the quantitative and qualitative data provided and results disseminated in a final research paper for VCU course university requirements and other vehicles as appropriate.</p> | |

STUDIES APPROVED BY EXEMPT PROCEDURES

| IRB # 2019-20 VECF Infant Toddler/Mental Health Support Network – LENA GROW | |
|--|-----------------------------------|
| Type of Submission | Modification #2 |
| Type of Review | Exempt under 45 CFR 46.101(b)(5)] |
| Agency Sponsor | Child Development Resources |
| Principal Investigator | Amy Bornhoft |
| PI Affiliation | Director of Training |
| Submitted | 7/22/2009 |
| Approved | 7/24/2009 |
| Modification | 7/11/2019; 12/23/2020 |
| Approval Ends | Continuing |
| Status | Continuing |
| <p>Description: The VDSS IRB initially approved IRB #2010-01 on July 24, 2009. The goal of the VA-ITSN is to achieve excellence in early care by increasing the educational level and skills of those who care for infants and toddlers, whether in family homes or in centers. It also serves to link existing community resources that support healthy, safe, and nurturing care for infants and toddlers. On July 12, 2019 the VDSS IRB approved a modification to the research to allow for the inclusion of topics and activities related to child mental health.</p> <p>On December 23, 2020 the VDSS IRB approved a second modification to the ITSN/MH project to allow for the inclusion of the LENA GROW program for the project. LENA Grow is a professional development program for early childhood educators that use regular feedback from LENA technology to improve the talk environment in the classroom. Coaching can be done one-on-one or in group sessions, weekly or every other week, depending on schedules. The coaching sessions provide time to review the data on the interactive talk environment in each classroom, and use the data to set goals to talk more. LENA uses a “talk pedometer” technology that provides objective data about language classroom development. This technology combined with 12 coaching sessions from Lena, TA and coaching from VA ITSN consultants and specialists allow programs to work with us and individual staff to set goals for ongoing program improvement regarding interactions and language development in the class.</p> <p>Permission would be obtained by the centers for the children to wear vests that hold the “talk pedometer.” The teachers in the class also have a pedometer and together it measures adult child interactions.</p> | |

| IRB # 2020-10 Virginia Child Care Provider Survey | |
|--|--|
| Type of Submission | Initial Request for Exemption |
| Type of Review | Exempt under 45 CFR 46.101(b)(5)] |
| Agency Sponsor | VDSS |
| Principal Investigator | Craig Burshem; Tara Ragland |
| PI Affiliation | Deputy Commissioner; Director Division of Licensing Programs |
| Submitted | 8/4/2020 |
| Approved | 8/6/2020 |
| Modification | NA |
| Approval Ends | Continuing |
| Status | Continuing |
| <p>Description: The survey by the Virginia Department of Social Services (VDSS) is for child day care providers, including center-based programs and family day home programs. The purpose is to get a broad perspective on how the Phase III child care re-opening guidelines related to the Covid-19 pandemic have affected the child care sector in Virginia and what the future impact may be. VDSS, its partner organizations, and policymakers will use the results to develop strategies to help child care providers in Virginia and improve upon existing solutions at the federal, state and community levels.</p> <p>The survey is administered via email with a link to the survey using the SurveyMonkey application. The email and link will be sent to child care programs (e.g., child day centers, religiously-exempt centers, family day homes, etc.) that have an email address listed with the VDSS Licensing unit. Only one response per center is requested. The first question asks for the respondent's name, child care program, and contact information for follow-up. The IP address and other individually identifiable information, however, will not be in the analysis file. The introduction to the survey describes the project's purpose and use of responses solely to inform statewide planning moving forward. No individual responses will be identified in the analysis or reporting of survey results.</p> | |

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 | | | |