

# DEPARTMENT OF SOCIAL SERVICES Office of the Commissioner

Kevin Erskine
Commissioner

November 3, 2025

#### **MEMORANDUM**

**TO:** The Honorable Glenn Youngkin

Governor of Virginia

Members, Virginia General Assembly

FROM: Kevin Erskine Ke En K

**SUBJECT:** Report on Human Research Activities

This report is pursuant to § 63.2-218, Code of Virginia which states:

The Board shall adopt regulations to effectuate the provisions of Chapter 5.1 (§ 32.1-162.16 et seq.) of Title 32.1 for human research, as defined in § 32.1-162.16, to be conducted or authorized by the Department, any agency or facility licensed by the Department, or any local department. The regulations shall require the human research committee to submit to the Governor, the General Assembly, and the Commissioner at least annually a report on the human research projects reviewed and approved by the committee and shall require the committee to report any significant deviations from the proposals as approved.

Please contact me with any questions (804) 726-7011.

KE:kc

Attachment

cc: The Honorable Janet V. Kelly, Secretary of Health and Human Resources



# ANNUAL REPORT ON HUMAN SUBJECTS RESEARCH

# Table of Contents

Annual Report on Human Subjects Research	İV
Report Mandate	iv
Executive Summary	iv
Definitions	V
Program Overview	v
Contacts	V
Authors	v
Background	1
Oversight Functions	1
IRB Administration	3
IRB Membership	3
IRB Activities in SFY 2025	3
IRB Administration and Membership	3
IRB Administration	3
IRB Membership	4
IRB Reviews and Approvals	4
IRB Reviews and Determinations, SFY 2021-2025	5
Board Meetings and Communication	6
Training and Technical Assistance	6
Policy Implementation	7
Conclusion	7
Appendix A. Mandate 🔗 section 63.2-218 Of The Code Of Virginia	8
Appendix B: IRB Member Roster, SFY 2025-2026	9
Appendix C: Studies Determined Exempt from IRB Review, SFY 2025	10
Appendix D: Modifications to Ongoing Studies Approved by the IRB, SFY 2025	12
Appendix E: IRB Meeting Minutes (March 4, 2025)	16

## ANNUAL REPORT ON HUMAN SUBJECTS RESEARCH

A Report for the Virginia General Assembly

October 1, 2025

#### REPORT MANDATE

Section <u>63.2-218</u> of the Code of Virginia requires the Virginia Department of Social Services (VDSS) human research committee to submit an annual report to the Governor, the General Assembly, and the Commissioner on the human research projects reviewed and approved by the committee. The Code also requires the human research committee to report significant deviations from the proposals as approved. This report documents State Fiscal Year (SFY) 2025 activities of the VDSS human research committee, known as the Institutional Review Board (IRB).

#### **EXECUTIVE SUMMARY**

The VDSS human research committee, known as the Institutional Review Board (IRB), ensures human subjects research will be conducted in compliance with federal and state statutes and regulations. In SFY 2025, there was turnover in the membership of the IRB for SFY 2025-2026, including the appointments of four new members. The IRB conducted 14 reviews and determinations for new and ongoing research studies. This included four studies that were determined exempt from IRB oversight.

In SFY 2025, the VDSS IRB initiated a discussion to clarify guidance about informed consent requirements. The discussion will continue into SFY 2026. The IRB Administrators streamlined its training requirements for new IRB members and added two new online courses from options available in CITI. Proposed changes to state code 22 VAC 40-890, regarding human subject research regulations, were approved by the Governor's Office and went into effect in February 2025.

#### About VDSS and the Institutional Review Board

The Virginia Department of Social Services (VDSS), in partnership with 120 local offices and community-based agencies across the state, delivers a wide variety of essential services and benefits to over 2.2 million Virginians each year. VDSS programs are designed to help Virginia's most vulnerable citizens find permanent solutions to life's many challenges. The goal is to promote the well-being of our citizens, to ensure families are strengthened, and individuals achieve their highest level of self-sufficiency.

The VDSS Institutional Review Board ensures that human subjects research carried out by the department and its affiliates protects the rights, welfare, and well-being of DSS clients and employees. The IRB achieves this by reviewing and approving research protocols that adhere to ethical principles and state and federal regulations and take steps to safeguard participants throughout the life of the study.

#### **DEFINITIONS**

#### Institutional Review Board

An internal ethics committee that reviews proposed human research studies to ensure that compliance with federal and state human research regulations. The essence of regulatory compliance is ensuring the protection of the rights, welfare, and wellbeing of individuals (e.g., clients, staff, stakeholders) who volunteer to participate in research. This is accomplished through IRB oversight of the research plan and the informed consent process.

#### Federal Wide Assurance (FWA)

The Federal Wide Assurance (FWA) is an assurance of compliance with federal regulations (e.g., 45 CFR 46 et seq.) for the protection of human subjects in research. Institutions (including state government agencies like VDSS) that conduct non-exempt human subjects research funded by the U.S. Department of Health and Human Services must register a FWA with the U.S. Office for Human Research Protections (OHRP).

#### PROGRAM OVERVIEW

The VDSS Institutional Review Board ensures that human subjects research carried out by the Virginia Department of Social Services (VDSS) and its partners protects the rights, welfare, and well-being of its clients and employees. This report covers the past year's activities.

#### **CONTACTS**

#### **AUTHORS**

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# ANNUAL REPORT ON HUMAN SUBJECTS RESEARCH

#### **BACKGROUND**

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 (OHRP), part of the U.S. Department of Health and Human Services, and will be subject to continuing review by the IRB. Since the mid-2000's, the VDSS IRB has been responsible for providing guidance and oversight to the human research protection program and for helping to maintain compliance with applicable federal (45 CFR 46 et seq.) and state (§32.1-162 and 22 VAC 40-890 et seq.) laws and regulations.

The VDSS IRB is responsible for protecting human research subjects in studies that utilize or seek to gather information about clients and employees of VDSS and the local departments of social services (LDSS). The IRB shall review human subjects research activities that are proposed, conducted, and/or authorized by VDSS, the LDSS, or VDSS-licensed facilities or contractors who are conducting research on behalf of the state agency. The IRB reviews research prior to implementation to ensure that the proposed research 1) protects the rights of clients and 2) maintains the privacy and confidentiality of information or data collected from participants.

Studies reviewed by the VDSS IRB fall under the category of social-behavioral research. Many studies approved by the IRB involve evaluation of delivery of program benefits and services to agency clients. Although the methods vary, customer/participant surveys, focus group interviews, and secondary data analysis of existing program data are most often employed. Risk of physical harm is unlikely for these types of studies. Most reviewed studies qualify as minimal risk to participants. Potential harm associated with a minimal risk study includes: 1) possible violations of subject privacy and loss of confidentiality of sensitive or personally identifiable information; 2) inequitable treatment or random assignment to study conditions; 3) coercion or lack of informed consent by the client; and, to a lesser extent, 4) mental discomfort or psychological harm activated by sensitive survey or interview questions.

#### **OVERSIGHT FUNCTIONS**

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 regulations prior to the commencement of the research. If the study is approved with conditions, the investigators are required to make modifications to the study prior to carrying out any research activities.

- 3. Require that information given to participants as part of informed consent is in accordance with appropriate laws, regulations, and best practices. 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 request a waiver of documentation) in accordance with federal and state laws and regulations.
- 5. In writing, notify investigators and their institution 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 document reasons for its decision in the written notification and give the investigator ample opportunity to respond in writing or in-person.
- 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. Starting July 1, 2022, if a study was initially approved under an Expedited review procedure, the study does not require a Continuing review in accordance with 46.109(f)(1) of the 2018 Revised Common Rule.
- 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 their affiliated institution.
- 8. Publish a summary of findings on the <u>VDSS IRB public web page</u> for each study previously approved under Expedited or Full Board review.

#### IRB ADMINISTRATION

The VDSS Commissioner serves as the Signatory Official for the state agency. As the head of the agency, the Commissioner is the Signatory Official for the agency's federal wide assurance (FWA). The agency's FWA (FWA00010976), which has been active since 2007, is registered with OHRP. By signing the FWA, the VDSS Commissioner assures that any human subjects research conducted by the state agency complies with federal regulations for the protection of human subjects in research. The VDSS IRB, which is housed within VDSS, has been active since 2006 and is also registered with OHRP (IORG0004422).

The VDSS IRB is overseen by the VDSS Office of Research and Planning (ORP), under the direction of the ORP Director. The ORP Director also serves as the agency's Data Ombudsman. The Data Ombudsman addresses grievances made against the IRB or human subjects research conducted by the Department.

Select staff members are assigned to perform administrative functions within the IRB, including providing guidance to researchers, assigning reviews to board members, facilitating board meetings, acting as the liaison between the IRB and research investigators, and performing exemption determinations.

#### **IRB MEMBERSHIP**

Per state administrative code (22 VAC 40-890-60), the IRB is required to have a minimum of five (5) active (voting) members of "varied backgrounds". The IRB's membership should be diverse in terms of demographics and professional background. Per state and federal regulations, the Board should have at least two individuals with a non-scientific or ethical background (e.g., lay professional, clergy, attorney). The current board has five non-scientific members, including direct service providers, program administrators, data governance experts, and local government agency leaders that serve populations of interest to VDSS. When there is change in the IRB membership, the Chairperson consults with other IRB members to recruit new members. All new and continuing appointments must be approved by the VDSS Commissioner.

## **IRB ACTIVITIES IN SFY 2025**

These activities were carried out by the VDSS IRB and its administrators between July 1, 2024, and June 30, 2025.

IRB ADMINISTRATION AND MEMBERSHIP IRB ADMINISTRATION

James Williams, MBA, MPP, who previously served as Virginia's Chief Deputy Secretary for Health and Human Resources under Governor Youngkin, was appointed as the VDSS Commissioner in July 2024. Commissioner Williams acts as the Signatory Official for VDSS. Under new leadership, VDSS updated its federal-wide assurance with OHRP on July 26, 2024. (The agency's FWA expires in July 2029.)

Two ORP staff members – Dr. Gail Jennings and Mr. Andrew Sell – were reappointed as administrators for the IRB. Dr. Jennings continues to serve as the chairperson for the board. With ample staffing, the IRB has continued to run smoothly and efficiently. The ORP Director, Dr. Robert Arons, was appointed to serve as the Department's Data Ombudsman.

#### IRB MEMBERSHIP

After a diligent search and vetting process, the Commissioner approved the appointments of 13 members to the board. Each member's term expires June 30, 2026. The IRB appointees have diverse educational and professional backgrounds and areas of interest. Nine appointees had previously served on the board during SFY 2022-2024. One new member from the Virginia Department of Education replaces a previous appointee who resigned. Representatives from three new member organizations -- the Virginia Joint Legislative Audit and Review Commission (JLARC), the Virginia Commonwealth University's Douglas S. Wilder School of Government and Public Affairs, and the Virginia Office of Data Governance and Analytics (ODGA) – provide fresh new perspectives to the board.

The VDSS IRB updated its board registration with OHRP on March 10, 2025. See Appendix B for a roster of the members appointed to the IRB for the SFY 2025-2026 term.

#### IRB REVIEWS AND APPROVALS

Using established regulatory criteria, the IRB may determine that a human subject research study 1) satisfies criteria for exemption from IRB oversight, 2) poses no more than minimal risk to subjects and is appropriate for expedited review, or 3) poses more than minimal risk to subjects and requires a full board review.

- Either the Chairperson or the IRB Administrator can determine if a study qualifies for exemption from IRB oversight under the federal regulations (45 CFR 46.104(d)).
- In an expedited review process, two board members typically the Chairperson and another board member – will review the proposal. Both reviewers must reach a consensus to approve the study with or without conditions or not approve the study. If either reviewer votes to not approve, the study is not approved. If there is a potential conflict of interest, the Chair may recuse themselves from voting and request that another board member serve as the secondary reviewer.
- In a full board review, a quorum of IRB members must convene to conduct a review the study and participate in an open vote. A simple majority of members present at the meeting must approve the study.
- Proposed modifications (i.e., changes) to an ongoing study may be approved through an *expedited* review process. This is called a "Modification review".

 Annual continuing reviews are required for ongoing studies that underwent an initial full board review. (2018 changes to the federal regulations no longer require continuing review for ongoing studies that pose no more than minimal risk and received an initial expedited review.)

#### In SFY 2025:

- The IRB did not receive any proposals that required an initial **Full Board** review.
- The IRB did not receive any proposals that required an initial **Expedited** review.
- The IRB approved nine (9) requests for approval of **Modification(s)** to ongoing studies.
- The IRB approved one (1) request to approve **Continuation** of an ongoing study.
- Four (4) studies were determined **Exempt** from IRB oversight under federal regulations described in § 45 CFR 46.104.

One study ("Evaluation of the CSE TANF Supplement"; PI: Sarah Smith, VDSS-Research and Planning), which was initially approved in SFY 2023, was completed and closed out in August 2024. There were no adverse events. Findings from each IRB-approved study are available on the VDSS IRB web page, under "Results of Approved Projects".

A brief description of IRB-exempt studies and study modifications are available in Appendices C and D. Table 1 shows the number of IRB reviews by review type in each state fiscal year. Including initial reviews, exemption determinations, and expedited reviews of study modifications and continuations, the IRB reviewed and approved fewer IRB proposals in SFY 2025 compared to SFY 2024.

### IRB REVIEWS AND DETERMINATIONS, SFY 2021-2025

Review Type	2021	2022	2023	2024	2025
Initial – Full Board	0	0	1	0	0
Initial - Expedited	1	7	11	0	0
Exemption Determination	3	4	9	7	4
Modification (Ongoing Study)*	6	1	20	18	9
Continuation (Ongoing Study)*	20	1	4	0	1
TOTAL REVIEWS	30	13	45	25	14

 $Source: VDSS\,IRB\,Tracking\,System\,(Access\,database).\ ^*Modification\,and\,continuing\,reviews\,can\,be\,conducted\,for\,ongoing\,studies\,approved\,in\,prior\,years.$ 

#### BOARD MEETINGS AND COMMUNICATION

The VDSS IRB is required to meet when there are studies that require a full board review and decision. At the discretion of the Chair, the IRB may discuss studies requiring expedited review to get more input from other board members. The Board may also convene ad hoc meetings when the administrators are considering policy or practice changes and request input from other board members.

Following soon after the new appointments, the VDSS IRB convened in-person on March 4, 2025, with a quorum of members attending. The VDSS Commissioner and Chief Deputy Commissioner (Kevin Erskine) were present to greet newly appointed members and reappointed members. In the absence of any studies requiring full board review, the meeting did not hold a vote. The agenda was mainly devoted to discussion of informed consent requirements regarding human subjects participating in research. A copy of the minutes for the March IRB meeting is in Appendix E.

#### TRAINING AND TECHNICAL ASSISTANCE

Per state regulations, IRB members are required to be trained on human research protection regulations and processes. The IRB Administrators continued its annual subscription with the Collaborative Institutional Training Initiative (CITI) to provide human research protection online training for DSS staff, IRB members, and new investigators. The IRB purchased supplemental courses that cover the IRB protocol review process and participant-centered informed consent guidelines. The training is offered at no charge to IRB members and research personnel.

In late 2024, VDSS kicked off a project to modernize its public website. The agency will transition to a new platform that makes the website's content more accessible (e.g., simple to read) and "hope centered" for visitors. Content managers in each division will have more creative control over making changes to their web pages.

As part of the VDSS public website, the <u>VDSS IRB home web page</u> and subpages inform visitors about the IRB's mission and role and serves as a repository for information (e.g., guidance manuals, quick guides, submission forms) about the IRB process used by research investigators and IRB members. Users will also find the link to CITI's training platform. Going into the next fiscal year, the IRB administrators will review and update IRB web content as part of the agency's overall web modernization initiative.

#### POLICY IMPLEMENTATION

During its last periodic review in November 2022, VDSS proposed amendments to Virginia Administrative Code 22 VAC 40-890 (Human Subject Research Regulations) that made the current state administrative code congruent with federal regulations (45 CFR 46) that were last revised in 2018. This action also updated citations and made technical changes for clarity. Those subject to the regulation would not be substantively impacted by the changes. The amendments were not expected to be controversial and were therefore appropriate for the fast-track rulemaking process. For more details about the amendments in the regulation, visit the <u>Virginia Register of Regulations</u>.

The State Board of Social Services approved the amendments on December 14, 2022. The amendments were approved by the Department of Planning and Budget on 1/23/2023 and by the Secretary of Health and Human Resources on 11/15/2024. The Governor's Office approved the changes on 12/6/2024. After a 30-day public comment period (no comments were received), the amendments went into effect on February 13, 2025.

No changes were proposed for <u>22 VAC 40-910</u> (General Provisions for Maintaining and Disclosing Confidential Information of Public Assistance, Child Support Enforcement, and Social Services Record) during the latest periodic review.

The IRB did not issue any new internal policy changes this year. At the last meeting of the IRB, the members embarked on a discussion of the current state and federal regulations, IRB policies, and VDSS practices that govern obtaining informed consent from DSS clients who are participants in human research. The priority for SFY 2026 is to continue this discussion with the objective of clarifying, if not revising, informed consent policy and practice. The Office of Research and Planning staff will conduct its own internal review of standard practices for obtaining client informed consent through the eligibility and services intake process.

#### **CONCLUSION**

All research approved by the IRB in SFY 2025 satisfied the regulatory definition of minimal risk and involved activities such as surveys, interviews, program evaluations, or secondary data analysis using DSS program administrative data. One of the priorities for SFY 2026 is to develop clearer guidance and improve processes for obtaining informed consent from DSS clients before engaging in research. The Chair will convene the IRB in early SFY 2026 to continue this discussion. The other priority is to continue modernizing the IRB web pages.

# APPENDIX A. MANDATE SECTION 63.2-218 OF THE CODE OF VIRGINIA

Section 63.2-218 of the Code of Virginia requires the Virginia Department of Social Services (VDSS) human research committee to submit an annual report to the Governor, the General Assembly, and the Commissioner on the human research projects reviewed and approved by the committee. The Code also requires the human research committee to report significant deviations from the proposals as approved. This report documents State Fiscal Year (SFY) 2024 activities of the VDSS human research committee, known as the Institutional Review Board (IRB).

# APPENDIX B: IRB MEMBER ROSTER, SFY 2025-2026

IRB Role	Name	Agency	Title
Administrator; Acting Chairperson	Gail C. Jennings, PhD	Virginia Department of Social Services, Office of Research and Planning	Senior Research Associate
Co-Administrator	Andrew Sell, MBA	Virginia Department of Social Services, Office of Research and Planning	Senior Research Associate
Member	Christine (Chris) Burroughs, CISSP	Virginia Office of Data Governance and Analytics	Director, Data Protection and Governance
Member	Christopher R. Campbell, MBA, MPA	Virginia Home for Boys and Girls, Advocacy and Program Advancement	Director
Member	Peter Gregory, MPA, MBA, PhD	Virginia Department of Juvenile Justice, Policy Division: Integrity, Data, and Research	Senior Research Associate
Member	Elsie Harper-Anderson, PhD	Virginia Commonwealth University; Wilder School of Government and Public Affairs	Associate Professor, Director of Ph.D. Program
Member	Carolyn Hawley, PhD	Virginia Commonwealth University, Department of Rehabilitation Counseling	Associate Professor
Member	Isaac Linde, MS	Virginia Department of Education	Survey Analyst
Member	Em Parente, PhD, LCSW	Virginia Department of Social Services, Division of Family Services	Assistant Director, Policies & Practice
Member	Timothy Reddish, MSW, MDiv	Commonwealth Catholic Charities	Program Supervisor
Member	Sarah Smith, PhD	Virginia Joint Legislative Audit and Review Commission (JLARC)	Methodologist
Member	Tamara Temoney-Porter, PhD	Hampton Department of Human Services	Agency Director
Member	Stephen Wade, MUP	Virginia Department of Social Services, Community and Volunteer Services	Health Equity Project Manager

Last updated 3/4/2025

# APPENDIX C: STUDIES DETERMINED EXEMPT FROM IRB REVIEW, SFY 2025

Title / Principal Investigator	IRB#	Determination Date	Summary
An Exploration of Potential Contributing and Preventative Factors of Child Welfare Profes- sional Burnout) (PI: Jeffrey Nitz, Liberty University)	IRB_2025-01	9/16/2024	This study examines factors (secondary trauma, adverse childhood experiences) that may contribute to and/or prevent burnout among child welfare professionals in Virginia. Local agency directors and Family Services Managers/Supervisors will email an invitation to 1,000 child welfare workers who have direct contact with clients to invite them to complete an anonymous survey. Two other public agencies outside of Virginia will also be asked to participate. The 72-item survey contains items from validated instruments (e.g., ACEs). No personally identifiable information will be collected. The survey is estimated to take approximately 15 minutes to complete. Respondents will have the opportunity to enter their name in a raffle drawing to win one of four \$50 VISA gift cards. There is no link between the survey responses and the information provided for the raffle drawing. The Liberty University IRB also determined this study to be exempt.
FYI (Foster Youth to Independence) Stakeholder Survey (PI: Letha Moore-Jones, VDSS-Family Services)	IRB_2025-02	12/5/2024	Partnering with Guidehouse, VDSS is conducting a stakeholder survey to gather feedback about Virginia's Foster Youth to Independence (FYI) program. The federally funded program provides Housing Choice Vouchers to youth aging out of foster care to provide them with stable housing, promote economic independence, and support them in their transition to adulthood. The 27-item survey will be sent to 1) youth over 18 who have aged out of foster care, 2) organizations providing case management/supportive services, 3) staff in Virginia local public housing agencies, and 4) Independent Living (IL) coordinators and other staff in the local departments of social services. Organizations in the foster care and housing ecosystems will forward the survey to youth over 18 exiting foster care where possible. The survey will also be announced at stakeholder meetings and within internal communications. There is no financial incentive to participate. Findings from the survey will be used to gain insights into the FYI program in Virginia and better understand stakeholder experiences with the program (e.g., challenges/successes in implementing and accessing the program).

Title / Principal Investigator	IRB#	Determination Date	Summary
DCSE SAVES Manassas Pilot Customer Experience Survey (Taylor Ashe, VDSS-Child Sup- port Enforcement)	IRB_2025	4/22/2025	Funded through SAVES, DCSE is launching a pilot program at the Manassas district office to implement and evaluate new practices and procedures designed to improve safe access to child support services by victims and survivors of domestic violence. Customers will be invited by email, letter, text message, and the customer portal to complete online surveys that assess how safe they feel while receiving child support services, both before and after the pilot program starts. The researchers will assess the effectiveness of new policies, practices, and staff training and identify areas of concern that still need to be addressed before full implementation. The survey focuses on three areas: understanding the child support filing/application process, safety and privacy concerns, and experience and trust in the child support system. The survey is anonymous; no personally identifiable information will be collected. Pre- and post-survey responses are not linked. Findings will be shared with the evaluator, the Center for Policy and Research (CPR). CPR will incorporate these findings into their evaluation of the Virginia SAVES project.
Empowering Caseworkers to Navigate the Benefits Cliff (PI: Sandra Lamm, VDSS-Research and Planning)	IRB_2025-04	6/6/2025	The "benefits cliff" phenomenon refers to when many low-income individuals receiving public assistance worry about losing some or all their benefits if they earn more income while in the program. Awareness of benefits cliff may strongly influence their decision to turn down promotions, more work hours, or better paying jobs. Benefits Program caseworkers can guide clients to anticipate income transitions and help them avoid unnecessary setbacks. This project seeks to equip caseworkers with the knowledge and tools they need to address these concerns and empower clients to make informed choices. In the first phase, project staff will conduct semi-structured interviews with 20 frontline caseworkers and their supervisors to assess their current level of understanding of the benefits cliff and their ability to effectively communicate this to clients. Workers will be asked if their clients ever considered the benefits cliff when making employment decisions. They will also be asked if they use any effective tools or guides. The interviews will be recorded, and observers will be present. Recordings will be transcribed and analyzed; personally identifiable information will be redacted. Findings from the interviews will be used by Workforce Development to create a training module on the Benefits Cliff.

# APPENDIX D: MODIFICATIONS TO ONGOING STUDIES APPROVED BY THE IRB, SFY 2025

Title / Principal Investigator	IRB#	Approval Date	Approved Modifications
Virginia Infant Toddler Support Network (VA-ITSN) and Early Childhood Mental Health (ECMH) (PI: Amy Stutt, Child Development Resources)	IRB_2019-20	6/12/2025	<ul> <li>Minor changes to 27 forms used by infant and toddler behavior consultants (ITBC) and infant and toddler specialists (ITS). Use of the revised forms will go into effect July 1.</li> <li>The Child Referral Form now asks the parent for preferred method of contact.</li> <li>Some forms have footnote information about the project inserted.</li> <li>The Program Orientation Guide, which was updated, will no longer be provided to parents and program sites if they withdraw from the program.</li> <li>The Coaching Evaluation form added one question.</li> </ul>
Kinship, Foster and Adoptive Families Survey (PI: Anya Horn- ing, VDSS-Family Services)	IRB_2022-08	2/10/2024	<ul> <li>The new PI is Anya Horning (Resource Family and Family Engagement Program Manager). Chanda Yarbrough (Resource Family Policy Specialist, VDSS Division of Family Services) is the other contact for the project.</li> <li>Changes were made to simplify survey questions and to collect more information to complete Virginia's Annual Report on the Five Year State Plan for Child and Family Services, which is submitted to the U.S. Department of Health and Human Services.</li> </ul>

Title / Principal Investigator	IRB#	Approval Date	Approved Modifications
A Randomized Trial of the Effects of SNAP Work Requirement Waivers on Program Participation, Labor Supply, and Well-being (PIs: Heeju Jang-Paulsen, VDSS-Research and Planning; Adam Leive, Harvard University)	IRB_2022-11	7/9/2024	<ul> <li>The study was also approved for continuation beyond July 2024.</li> <li>One of the co-Pls, Dr. Tim Layton, is transferring to the University of Virginia.</li> <li>The project initially planned to enroll ABAWDs aged 18 to 49. However, last year's Fiscal Responsibility Act (FSA) increased the age limit for work requirements. The age qualification for study enrollment was adjusted.</li> <li>ABAWDs with recertification periods greater than 6 months are required to submit an interim report (IR) every six months. The IR due date is auto set in VaCMS. However, it was discovered in June 2024 that the system was not automatically assigning the IR due date for the study enrollees in Intervention Groups 3 and 4, whose recertification period should be extended to 12 months. Business Operations is including a system correction in the August VaCMS release.</li> <li>The project team noticed that 30% of cases in Intervention Groups 3 and 4 had shorter renewal periods than what was assigned for their group (6 months instead of 12 months). The Pls hypothesize that case workers may be manually resetting the due dates in VaCMS. They have asked Business Operations to investigate this issue.</li> <li>The MOU/DSA between VDSS, Harvard, and University of California-Berkeley to analyze administrative data is under review by the Office of the Attorney General.</li> </ul>
A Randomized Trial of the Effects of SNAP Work Requirement Waivers on Program Participation, Labor Supply, and Well-being (PI: Heeju Jang-Paulsen, VDSS-Research and Planning; Adam Leive, Harvard University)	IRB_2022-11	1/17/2025	<ul> <li>The study will conduct a survey of study enrollees to gauge how well clients understand the SNAP work requirement rules for continued benefit eligibility. A link to the online survey will be sent by text or email to a random sample of study participants who have been enrolled in the study five months prior to the survey. Clients' contact information will be shared with Harvard's survey contractor, SSRS.</li> <li>The IRB is waiting to receive a signed copy of the MOU/DSA. As of 2/19/2025, the agreement covers the period of 2025-2027. The contract further states that the study team (Harvard and SSRS) will verify addresses and other contact information using Lexus-Nexus search databases. SSRS will employ multiple methods of disseminating the survey (e.g., email, mail, SMS text, phone). Any breach of confidentiality shall be reported to the VDSS Chief Information Security Officer within 24 hours of discovery.</li> </ul>

Title / Principal Investigator	IRB#	Approval Date	Approved Modifications
Energy Assistance Program (EAP) Cooling and Heating Surveys (PI: Sandra Lamm, VDSS-Research and Planning)	IRB_2023-04	7/10/2024	One of the co-PIs, Sarah Smith, resigned from VDSS in summer 2024. The sole principal investigator is Sandra Lamm.
Energy Assistance Program (EAP) Cooling and Heating Surveys (PI: Sandra Lamm, VDSS- Research and Planning)	IRB_2023-04	10/2/2024	As a continuation of a previous request (approved 6/28/2024), the EAP will conduct a stand-alone pilot that has EAP workers administer the EAP Cooling Survey by telephone. As a proof-of-concept test, 50 randomly selected English-speaking clients who received cooling assistance in FFY 2024 will be notified in advance by email. EAP personnel will make three attempts to reach clients and administer the survey by phone. The worker will obtain verbal consent. The EAP worker will record answers in Qualtrics. During the consent process, the interviewer will ask for the client's permission to use their case ID for linking survey responses to administrative data. This will reduce the length of the survey by eliminating the need to ask for demographic and case information already available in VaCMS.
Fostering Responsible Parents in Virginia (PIs: Mariellen Keely and Taylor Ashe, VDSS-DCSE)	IRB_2023-11	7/19/2024	Changes to the study team. Also, the study received a no-cost extension from the federal funder. The project period has been extended to 6/30/2025.
Noncustodial Parent Barriers to Payment Survey (PI: Gail Jen- nings, VDSS-Research and Planning)	IRB_2024-09	8/8/2024	The PI, Sarah Smith, resigned from VDSS, effective August 9, 2024. Gail Jennings in the Office of Research and Planning will assume the role of PI. The modification was reviewed by the other IRB Administrator.

Title / Principal Investigator	IRB#	Approval Date	Approved Modifications
Noncustodial Parent Barriers to Payment Survey (PI: Gail Jen- nings, VDSS-Research and Planning)	IRB-2024-09	3/7/2025	<ul> <li>The study team received approval from the DCSE Clearinghouse to provide a script to the DCSE Call Center and to inform field staff about the study.</li> <li>At the request of DCSE's legal team, the survey invitation includes stronger language regarding protection of data privacy. Research subjects are instructed to contact the Call Center, instead of survey administrators, if they want to discuss the specifics of their child support case. They are informed that if they provide any information that personally identifies them, it will be considered voluntary disclosure.</li> </ul>

### **APPENDIX E: IRB MEETING MINUTES (MARCH 4, 2025)**

**Date and Time:** March 4, 2025, 10:00-11:00 am

**Location:** VDSS Home Office (5600 Cox Road, Glen Allen, VA 23060)

DSS New River Conference Room #386

Microsoft Teams Need help?

Join the meeting now

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Members Present: Gail Jennings (VDSS, IRB Chairperson), Andrew Sell (VDSS, IRB Adminis-

trator); Christine (Chris) Burroughs (ODGA), Chris Campbell (VHBG), Peter Gregory (DJJ), Elsie Harper-Anderson (VCU), Carolyn Hawley (VCU), Isaac Linde (VDOE), Stephen Wade (VDSS). Tamara Temoney-Porter (Hampton Department of Human Services), Tim Reddish (CCC). **ABSENT:** Em

Parente (VDSS), Sarah Smith (JLARC)

Guests: Robert Arons (VDSS), Hari Dulal (VDSS), Commissioner James Williams

(VDSS), Kevin Erskine (VDSS), HeeJu Jang-Paulsen (VDSS)

#### **OLD BUSINESS/ANNOUNCEMENTS:**

- 22 VAC 40-890 (Human Subject Research Regulations) underwent a Fast track review initiated in 2020-2021. ORP proposed changes to several sections to align the state code with federal regulations (Common Rule: 45 CFR 46) that were revised in 2018. The rule changes were published in the <a href="Virginia Register">Virginia Register</a> in January 2025 (no comments received). The changes became effective in February.

#### **EXPEDITED REVIEW:**

None brought before the board.

#### **FULL BOARD REVIEW:**

None brought before the board.

#### **EXEMPT DETERMINATIONS:**

- "An Exploration of Potential Contributing and Preventative Factors of Child Welfare Professional Burnout" (#IRB\_2025-01) -- The purpose of the study is to examine factors that may contribute to and/or prevent burnout among child welfare professionals in Virginia. Child welfare workers will be asked to complete an anonymous online survey.
- "FYI (Foster Youth to Independence) Stakeholder Survey" (#IRB\_2025-02") -- VDSS is conducting a stakeholder survey to gather feedback about Virginia's Foster Youth to Independence (FYI) program, which provides housing vouchers to youth aging out of foster care. The goal is to prevent homelessness, promote economic independence, and support them in their transition to adulthood.

#### **MODIFICATIONS & CONTINUATIONS:**

- "Kinship-Foster-Adoptive Families Survey" (#IRB 2022-08)
- RCT SNAP Work Requirements Study (#IRB 2022-11) modification and continuation
- EAP Heating and Cooling Surveys (#IRB 2023-04) Two (2) modifications
- "Fostering Responsible Parents in Virginia" (#IRB\_2023-11)
- "Non-Custodial Parents Barriers to Payment Survey" (#IRB 2024-09)

#### **NEW BUSINESS:**

- Welcome to New Appointees and Continuing Appointees
- Opening Remarks from Commissioner Williams
- Overview of the VDSS IRB Purpose, Roles/Responsibilities, Training, and Communication
- Discussion regarding informed consent practices and possible changes.

#### **NEW BUSINESS DISCUSSION SUMMARY:**

Commissioner welcomed everyone, introduced himself, then asked everyone to introduce themselves.

Members and guests introduced themselves.

Commissioner spoke about the IRB. Understands the importance of research. He called the meeting for a 'refresh' of the IRB. It serves a vital function, wants the IRB to be best in class. Bob and Hari have been doing a great job. May want some slight changes since it is such a large group. In hindsight, we should have fewer IRB members. (The current state regulations require a minimum of 5 members on the board.) Wanted to have discussion after Gail provided more information on how the IRB currently operates. Turned it over to Gail who presented an overview of the agency's IRB background and current processes.

Gail asked for questions. A question was asked about how many full or expedited reviews have been done recently. Gail responded that there had been a spike a few years ago during the public health emergency but that it's been dropping off lately. There have been less than five full board reviews in the history of the IRB back to 2012. Most members are involved in carrying out expedited reviews. Gail welcomes the opportunity to have board members be more involved in the IRB decision-making (e.g., exemption determinations) and yet not pose a burden on members' time and effort.

Commissioner asked members if they knew of any best practices implemented at other IRBs they had served on or knew. Stephen asked whether a client had served on the board. Gail had not been aware of that being the case. Christopher mentioned that he was aware of other boards (beyond IRBs) that had those with 'lived experience' on their boards. Gail responded that having a client on the board was a good idea.

A IRB member inquired about required human research protection training for IRB members. Gail informed them that they should complete the Human Subjects Research series offered by CITI. Training at their host institution would be an acceptable substitution. Gail also recommended that they complete the OHRP "Participant-Centered Informed Consent" course and the "IRB Review Protocol" course offered through our CITI subscription.

Commissioner brought up a concern about the "lack of informed consent" for the

RCT SNAP Work Requirements Study (#IRB\_2022-11). When asked, Gail informed him that the study was reviewed by two members outside of VDSS (a LDSS director and a VCU researcher), specifically, to address his concerns about potential conflict of interest). He does not support the IRB approving the waiver of informed consent for this study, specifically, for sharing clients' contact information with the Harvard researchers and their contractor (SSRS) so that they can disseminate a survey. One suggestion is to give SNAP recipients the opportunity to opt out at the local level.

Chris Burroughs (ODGA) mentioned that she has information she can share about Virginia's data privacy laws (<u>Virginia Data Collection and Dissemination Practices Act</u>). She provided a link to the administrative code after the meeting. Gail will organize a follow-up meeting with ODGA and/or AOG. Kim Piner in the Office of the Attorney General (OAG) was mentioned as the right contact for this follow-up meeting.

Andrew asked whether it was the Commissioner's position that we should stop allowing for waivers of informed consent that are permitted within the federal regulations. Commissioner said that was right and it should be stopped. It introduces legal risk. It's a way to solve the problem

Commissioner finds the Benefit Program enrollment/intake form saying that clients may be involved with program research is fine but doesn't get at a higher standard than broad consent based on the Helsinki principles. Perhaps allow opt out during annual renewal process.

Christopher asked if we can do any research with children? Discussion was had around parental consent and difficulty of getting informed consent from parents for those children who have had parent rights terminated, etc. Gail mentioned that current policy is that LDSS staff will not be able to consent on behalf of children in their care.

Commissioner mentioned that implementing informed consent can prevent research but we shouldn't not do it just because it's inconvenient.

HeeJu discussed the details of her RCT SNAP Work Requirements Study (#IRB\_2022-11) and asked questions about how to adjust her study's protocol given the new requirement to provide informed consent prior to the survey being sent. Commissioner clarified that conducting administrative data research in-house (internally) is fine. Biggest issue is violating Virginia privacy laws. HeeJu mentioned that administrative changes would need to be made to address this change. Could a text communication to clients address this issue of obtaining informed consent prior to the survey being sent?

Commissioner's position is that text message sent to those enrolled in study is fine. Without something like this, we are violating people's privacy rights under Virginia law if they get the survey (without informed consent). Need to send notification prior to survey being sent to them.

Commissioner referenced how the VA Tax Department says no to research due to concerns about risk. We should continue to do research but if we are going to enroll clients in a research project, they should have prior informed consent.

#### Action Items:

• Gail to coordinate with Chris Burroughs to schedule follow-up meeting to review latest Virginia data privacy laws.

- Adjustments will be made to RCT SNAP Work Requirements Study (#IRB\_2022-11) to obtain informed consent prior to the survey being sent to enrolled study participants.
   VDSS IRB will no longer approve requests for waivers of informed consent per the Com-
- missioner's position.

#### **OTHER BUSINESS:**

#### **ADJOURNED TIME:**

The meeting adjourned at 11:01 am.

#### MOTION:

#### N/A

#### **DECISION AND VOTING:**

DECISION	ECISION AND VOTING:							
Present	Scientist (S) Non-sci- entist (N)	IRB Member (Organization	า	In person (I) - default Teleconference (TC) Telephone (TP)				
	S	Gail Jennings, PhD (Chair	person)	I				
	S	Andrew Sell, MBA (Admin	istrator)	I				
$\square$	N	Christine (Chris) Burrough		I				
$\boxtimes$	S	Christopher Campbell, MB Boys and Girls)	BA, MPA (VA Home for	1				
$\boxtimes$	S	Peter Gregory, PhD (DJJ)		I				
	S	Elsie Harper-Anderson, Pl	nD (VCU)	I				
$\square$	S	Carolyn Hawley, PhD (VC	U)	1				
	S	Isaac Linde, MA (VDOE)	I					
	S	Em Parente, PhD, LCSW						
$\boxtimes$	N	Tim Reddish, MSW, MDiv olic Charities)	тс					
	S	Sarah Smith, PhD (JLARC						
$\boxtimes$	S	Tamara Temoney-Porter,	1					
$\boxtimes$	N	Stephen Wade, MUP (VD	I					
Additional	l Participants	s: Name	Role during the meeting	g:				
James Williams (VDSS Commissioner)  Kevin Erskine (VDSS Chief Dep. Commissioner)  Hari Dulal (VDSS Dep. Commissioner)  Robert Arons (VDSS ORP Director)  Heeju Jang-Paulsen (VDSS ORP)			Opening remarks					