



# COMMONWEALTH of VIRGINIA

## DEPARTMENT OF SOCIAL SERVICES

### Office of the Commissioner

James Hunter Williams  
Commissioner

December 9, 2024

#### MEMORANDUM

**TO:** The Honorable Glenn Youngkin  
Governor of Virginia  
  
Members, Virginia General Assembly

**FROM:** James H. Williams *James Williams*

**SUBJECT:** Report on Human Research Activities

This report is pursuant to § 63.2-218, 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.


JW:kc  
Attachment

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



# Annual Report on Human Subjects Research

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# ANNUAL REPORT ON HUMAN SUBJECTS RESEARCH

A Report for the Virginia General Assembly

October 1, 2024

## REPORT MANDATE

*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).*

## 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 2024, the IRB conducted 25 reviews and determinations for new and ongoing research studies. This included seven studies that were determined exempt from IRB oversight. In addition, the IRB implemented a new policy requiring that investigators and their research staff be current on their human research protection training, while the study is under review or ongoing. The membership of the IRB has remained stable over the last two years. There were significant changes in leadership at VDSS, including the appointment of a new Commissioner (James Williams, former SHHR Deputy Secretary). The new Commissioner is considering making new appointments to the IRB in SFY 2025.

In FY 2024, the VDSS IRB engaged in educating state staff about the necessity of human research protection and the IRB's oversight role. Going into the next year, the IRB will start the process of purchasing an online system for IRB management that the submission and review processes more efficient for administrators, board members, and research investigators.

### About VDSS and the Institutional Review Board

The Virginia Department of Social Services (VDSS) partners with local departments of social services and community organizations, to promote the well-being of children and families across the Commonwealth. We proudly serve alongside nearly 13,000 state and local human services professionals throughout the Social Services System, who ensure that thousands of Virginia's most vulnerable citizens have access to the best services and benefits available to them.

Together, we work each day to serve, empower, and create opportunities for brighter futures.

The VDSS Institutional Review Board ensures that human subjects research carried out by VDSS and its partners protects the rights, welfare, and wellbeing of its clients and employees.

## **DEFINITIONS**

### *Institutional Review Board (IRB)*

An internal committee that reviews proposed human research studies to ensure 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 the U.S. federal regulations (e.g., 45 CFR 46 et seq.) for the protection of human subjects in research. Institutions conducting human subjects research that is federally funded by the U.S. Department of Health and Human Services must register a FWA with the U.S. Office for Human Research Protections.

## **PROGRAM OVERVIEW**

The VDSS Institutional Review Board ensures that human subjects research carried out by VDSS and its partners protects the rights, welfare, and wellbeing of its clients and employees. This report covers the past year's activities.

## **CONTACTS**

### **AUTHOR**

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# Annual Report on Human Subjects Research

## SECTION 1: 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 federal [Office of Human Research Protections](#) (OHRP) 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 [22VAC40-890](#) 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: possible violations of subject privacy and loss of confidentiality of sensitive or personally identifiable information; inequitable treatment or random assignment to study conditions; coercion or lack of informed consent by the client; and, to a lesser extent, mental discomfort or psychological harm triggered 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 [VDSS IRB public web page](#) for each study previously approved under Expedited or Full Board review.

## **IRB ADMINISTRATION**

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 VDSS Commissioner serves as the Signatory Official for the agency. ORP staff members perform administrative functions within the IRB, including chairing the committee, convening the board meetings, communicating with board members 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 seven (7) 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, and agency leaders that serve populations of interest to VDSS. When there is changeover 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.

## SECTION 2: IRB ACTIVITIES IN SFY 2024

These activities were carried out by the IRB and its administrators between July 1, 2023, and June 30, 2024.

### IRB REVIEWS AND APPROVED STUDIES

Using established regulatory criteria, the IRB may determine that a study 1) satisfies criteria for exemption from IRB oversight, 2) is appropriate for expedited review by the Chairperson and one or more experienced reviewers, or 3) requires full board review. Generally, the IRB Chairperson or one or more experienced reviewers conducts expedited reviews; the Chairperson or an IRB Administrator makes exemption determinations. For a full board review, a quorum of IRB members must be present to meet and review the study. A simple majority of members present at the meeting must approve the study.

Compared to SFY 2023, the IRB reviewed significantly fewer IRB submissions (including initial reviews, exemption determinations, modifications, and continuations) in SFY 2024 (25 versus 45). In SFY 2024:

- No studies underwent a **Full Board** review in SFY 2024. Any study that has activities that pose more than a minimal risk to human subjects or do not fall within the categories approved for expedited review procedures require a **Full** review and approval by a simple majority of board members in attendance.
- No studies underwent **Expedited** review, as described in 45 CFR 46. Expedited reviews are performed by the IRB Chairperson or by one or more other experienced reviewers designated by the Chair.
- On eighteen (18) occasions, previously approved studies requested approval of **Modification(s)** to their protocols.



- No studies required a **Continuing Review**. In accordance with a section of the 2018 revised Common Rule ([46.109\(f\)\(1\)](#)), studies approved under Expedited Review do not require a Continuing Review. Starting in SFY 2023, new studies initially approved by the VDSS IRB under an expedited review process do not require an annual continuing review unless the IRB decides otherwise.
- Seven (7) studies were deemed **Exempt** from IRB oversight under federal regulations described in 45 CFR 46. The IRB Chairperson or an Administrator may conduct Exemption Determinations, reviews of Modifications, and Continuing Reviews.

A brief description of IRB-exempt studies and study modifications are available in Appendices A and B. Table 1 shows the breakdown of IRB reviews by state fiscal year.

*Table 1: Annual Number of IRB Reviews & Determinations, SFY 2020-2024*

Review Type	2020	2021	2022	2023	2024
Initial – Full Board	0	0	0	1	0
Initial - Expedited	2	1	7	11	0
Exemption Determination	4	3	4	9	7
Modification (Ongoing Study)*	2	6	1	20	18
Continuation (Ongoing Study)*	2	0	1	4	0
<b>TOTAL REVIEWS</b>	<b>10</b>	<b>10</b>	<b>13</b>	<b>45</b>	<b>25</b>

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

Two (2) studies, which were initially approved in SFY 2023, were completed and closed out during SFY 2024. Findings from each study are available on the [VDSS IRB web page](#), under “Results of Approved Projects”.

- “Immigrant Access and Participation in DSS-Sponsored Education and Training Programs” (#IRB\_2023-02). Principal Investigator(s): Sarah Smith, PhD (Research and Planning, VDSS). Sponsored by the VDSS Office of New Americans (ONA). The study was initially approved on 9/20/2022. No adverse events were reported.
- “DCSE Paternity Establishment Project” (#IRB\_2023-20). PI(s): Sandra Lamm, PhD (Research and Planning, VDSS). Sponsored by the VDSS Division of Child Support Enforcement (DCSE). The study was initially determined exempt on 6/28/2023.

## CHANGES IN IRB STAFF AND MEMBERSHIP

### *IRB Administration*

Three ORP staff members – Drs. Gail Jennings and Aline Jesus Rafi and Mr. Andrew Sell – perform the day-to-day operations of the IRB. Dr. Jennings also chairs the Board meetings. With ample staffing, the IRB has continued to run smoothly and efficiently.

In SFY 2024, there were two noteworthy changes in staffing that potentially impact IRB operations. First, Robert Arons was hired in November 2023 as the ORP Director, replacing Dr. Jeff Price who left in June 2023 to take a new position at the Virginia Department of Transportation. Dr. Arons holds a Ph.D. in Economics from the University of Rochester and B.A. in economics from Case Western Reserve University. Professionally, Dr. Arons has held significant roles in Freshwater Economics, where he led initiatives in economic analysis and business development. Prior to that, he was an Associate Director and Senior Economist at Secretariat Economists, where he conducted financial and economic modeling and policy analysis. His public sector experience includes six years as a Staff Economist at the Department of Justice's Antitrust Division, where he engaged in economic analysis, market definition, and data management.

Second, in April 2024, Dr. Danny Avula resigned as the VDSS Commissioner after serving two years in this role. James Williams, MBA, MPP, who previously served as the Chief Deputy Secretary of Health and Human Resources, was appointed the VDSS Commissioner in July 2024. As the head of the agency, Commissioner Williams is the Signatory Official for the agency's federal wide assurance (FWA). The FWA is registered with the Office for Human Research Protections (OHRP) in the U.S. Department of Health and Human Services. In July, the FWA was updated to include new information about the Signatory Official and the office's new location.

### *IRB Membership*

During SFY 2024, the IRB functioned with 13 voting board members, including Dr. Jennings, Dr. Rafi, and Mr. Sell, who perform IRB administrative duties. The IRB appointees have diverse educational and professional backgrounds and areas of interest. Members include representatives from other state government agencies (Departments of Juvenile Justice and Behavioral Health & Developmental Services), local government (Hampton Department of Social Services), academic and research institutions (e.g., Virginia Commonwealth University), and community-based agencies serving at-risk children and youth (Virginia Home for Boys and Girls and Commonwealth Catholic Charities). See Appendix C for the IRB member roster. Each appointee's term ended on June 30, 2024.

The members' appointments are renewable for another new term, upon approval by the Commissioner. At the end of the state fiscal year, all but two existing members expressed interest in being reappointed to the IRB. In SFY 2025, the Commissioner is considering new additional appointments to the board. The IRB will consider the matter of filling the seats of the two departing members.

## **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 a policy or practice change and request input from the board members.

During SFY 2024, the VDSS IRB convened virtually (through Microsoft Teams) on June 25, 2024, with a quorum of members present. In the absence of any studies requiring full board review, the June meeting did not require any vote. The agenda was devoted to discussion of the recent change in leadership at the host agency. The Board members provided input about the responsibilities of the Signatory Official and agency Ombudsman and who may serve in these roles at the agency. A copy of the June 25<sup>th</sup> meeting minutes is in Appendix D.

## **TRAINING AND TECHNICAL ASSISTANCE**

### *New IRB Determination Tool for Investigators*

The IRB administrators launched a new online tool (“Human Research Determination – Decision Assistance Tool”) as a decision-making aid for researchers and investigators. Designed as a Qualtrics survey, the user answers questions, progressing through different pathways leading to different conclusions. The tool is intended to help state and local DSS staff and external researchers decide if their data collection and data analysis project meets the federal definition of “human subjects research”, which requires IRB oversight. This tool is not meant to replace a formal and official determination by the IRB. However, it may assist individuals who may be unsure whether their project requires contact with the IRB prior to starting a project. The tool is adapted from one created by Loyola University-Maryland. A link to the tool is available on the IRB public website.

ORP staff announced availability of the Human Research Determination-Decision Assistance Tool through internal broadcasts to VDSS and LDSS employees. Also, the tool was presented by ORP staff at a VDSS employee meeting in November 2023. As of July 2024, investigators for 14 data collection projects have used the Decision Assistance Tool.

### *IRB Awareness and Training*

ORP staff briefly gave an overview of the role of the IRB at a November 2023 state staff meeting for VDSS employees. The IRB Chair also discussed the role of the IRB in research oversight at a training conducted by the Office of Innovation and Strategic Initiatives in February 2024.

## **POLICY IMPLEMENTATION**

### *New Training Requirements for Investigators*

Effective July 1, 2023, principal investigators, co-investigators, and other research personnel involved in research under review by the VDSS IRB must complete a valid human research protection (HRP) training or show evidence of completed training (e.g., certificate) before the study is approved by the IRB. After study approval and before study completion, it is the responsibility of the study's Principal Investigator to ensure that all research personnel maintain valid HRP training. For those who cannot obtain HRP training at their host institution, VDSS offers access to free training through their annual subscription to CITI (Collaborative Institutional Training Initiative), a major provider of web-based Human Research Protection (HRP) training.

## **CONCLUSION**

All research approved by the IRB in SFY 2024 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. Priorities for SFY 2025 are as follows:

- Continue to promote the CITI as the preferred source for human research protection training to DSS staff, IRB members, and new investigators.
- Encourage use of the new Human Subjects Research decision-making tool for new investigators.
- Obtain approval for purchasing a SaaS (software as a service) solution for full life-cycle management of IRB submissions and ensure that the cloud platform meets agency and state IT security requirements. If approved, ORP will purchase an annual subscription, set up the platform, and provide training to end users. The new solution will replace the IRB's standalone Microsoft Access database and ensure that the IRB submission, review, and data entry processes are done more quickly and efficiently.
- Appoint new members to the IRB who will fill in gaps in representing the interests of key vulnerable populations (e.g., preschool-age and school-age children, people with disabilities).

## **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-EXEMPT STUDIES, SFY 2024

- *Building a Stronger Child Care System in Virginia: Virginia Family Survey (IRB\_2024-01)*: Using administrative data and surveys, the UVA study collects data about families' experience with finding and using early care and education for their children (up to 3 years old). This survey also asks families about their use of subsidized child care through the VDSS Child Care Subsidy Program (CCSP). UVA will use Child Care Subsidy administrative data in VaCMS to identify families that qualify for the study.
- *A Discussion on Parenting Children and Youth Who Have Experienced the Child Welfare System (IRB\_2024-02)*: The purpose of a student-led research project is to pilot a new parent coaching approach at a local department of social services (Newport News). Permanency staff will be trained to deliver the Managing Adoptive and Resource Family Parent Family Expectations (MARFPE) Coaching Model, and then asked to implement the coaching model with Adoptive and Foster Parents. Staff will use the new coaching model to help build resource parents' capacity to effectively support children and youth in their care.
- *Survey of Vicarious Trauma in the DSS Human Services Workforce (IRB\_2024-03)*: The VDSS Office of Trauma and Resilience Policy (OTRP) is surveying frontline workers and supervisors in Benefit Programs and Family Services at local agencies about the impact of vicarious trauma on the human services workforce, as well as coping strategies and agency-driven efforts for mitigating vicarious trauma.
- *Virginia Department of Social Services Employee Engagement Study 2023 (HOPE Survey) (IRB\_2024-04)*: Partnering with the University of Oklahoma, OTRP is surveying state DSS employees about how hope, a goal-oriented way of thinking related to our well-being, relates to VDSS staff job experiences and measures of well-being, including job satisfaction, burnout, and stress.
- *Obstacles to and Facilitators of Services in Child Welfare in the Context of the Family First Prevention Services Act (IRB\_2024-05)*: As part of an evaluation of the Family First Prevention Services Act, this focus group study will examine client retention across service pathways, specifically, factors that may positively or negatively impact a family from being referred for in-home services, starting services, and completing services. The VCU researchers will interview Service planners at local DSS offices (e.g., case managers/workers, CSA workers, staff on FAPT teams), state DSS staff, families (primary caregivers only), and providers (e.g., therapists).
- *Longitudinal study of factors associated with retention among state child welfare stipend program participants (IRB\_2024-08)*: VCU is conducting a longitudinal research study to identify where Child Welfare Stipend Program (CWSP) alumni are employed and factors that may be linked with decisions to remain in or leave child welfare-related practice. All alumni who graduated between 2017-2024 are invited to participate by completing an online survey.

- *Noncustodial Parent Barriers to Payment Survey (IRB\_2024-09)*: On behalf of the Division of Child Support Enforcement, ORP is conducting a survey of noncustodial parents (NCPs) regarding barriers to meeting their monthly child support obligations. The program's mission is to promote family well-being through the collection and distribution of child support; understanding the factors that influence NCP payment behavior will help DCSE to improve programs and services to support its mission.



## APPENDIX C: IRB-APPROVED MODIFICATIONS, SFY 2024

Title / Principal Investigator (PI)	IRB #	Modification Approval Date	Proposed Modifications
Virginia Infant Toddler Support Network (VA-ITSN) and Early Childhood Mental Health (ECMH) (PI: Amy Stutt, Child Development Resources)	IRB_2019-20	10/30/2023	Request a change in the forms used by the Infant and Toddler Behavior Consultants (ITBC) when evaluating coaching offered to parents and providers. The forms allow for electronic signatures.
Virginia Infant Toddler Support Network (VA-ITSN) and Early Childhood Mental Health (ECMH) (PI: Amy Stutt, Child Development Resources)	IRB_2019-20	6/5/2024	<ul style="list-style-type: none"> <li>• Change its name to "Virginia Infant &amp; Toddler Specialist Network (VA ITSN) and Infant Toddler Behavior Consultation (ITBC)".</li> <li>• Modify forms and allowing forms to be completed electronically through use of tablets.</li> <li>• Only allow capture of photos and videos by parents.</li> <li>• Retain study records in secure (locked) locations at the ITSN regional offices and restrict access to the consultant and/or supervisor for three years after termination of ITSN activities (otherwise, send records to the VA ITSN Central Office).</li> </ul>
Recruiting and Retaining Virginia School Mental Health Providers: Evaluating the impact of grant funded activities (PI: Isaac Linde, Virginia Department of Education)	IRB_2022-05	2/6/2024	<ul style="list-style-type: none"> <li>• Change to the Principal Investigator.</li> <li>• Change in storage and access to the study data. The data will be accessible to both the VDOE research team and UVA collaborators. Consent form was updated. Only those participants who provide consent on the modified form will have their data shared with the University of Virginia research teams.</li> </ul>
PJAC Equity Research Supplement (PI: Melanie Skemer, MDRC)	IRB_2022-07	8/25/2023	<ul style="list-style-type: none"> <li>• Change to the study's name.</li> <li>• New round of interviews with staff, legal partners, and non-custodial parents from the original study's control group to</li> </ul>

Title / Principal Investigator (PI)	IRB #	Modification Approval Date	Proposed Modifications
			<p>analyze disparities in punitive enforcement actions. Parents will be recruited by email or mail. (None can have a history of domestic violence in their case record.)</p> <ul style="list-style-type: none"> <li>Interviews will be conducted by phone or virtually (via Zoom). A waiver of documented consent was approved.</li> <li>Study data collection is extended through 12/31/2024.</li> </ul>
PJAC Equity Research Supplement (PI: Melanie Skemer, MDRC)	IRB_2022-07	10/10/2023	<ul style="list-style-type: none"> <li>Change to recruitment materials and consent forms for the staff and partner interviews that were previously approved on 8/25/2023.</li> </ul>
Energy Assistance Program (EAP) Cooling and Heating Surveys (PI: Sandra Lamm, VDSS)	IRB_2023-04	9/6/2023	<ul style="list-style-type: none"> <li>Two additional waves of the survey (one for the Cooling season and the other for the Heating season). Project extended to January 1, 2026.</li> <li>Respondents can complete the survey by phone with assistance by EAP staff, as an alternative to the online option. Consent will be obtained verbally; a waiver of written informed consent was approved.</li> <li>Clients will be informed about the survey through their Benefit award notifications sent via USPS.</li> <li>Minor changes to the survey questionnaire. The telephone version contains additional instructions for EAP workers conducting the telephone interview.</li> </ul>
Energy Assistance Program (EAP) Cooling and Heating Surveys (PI: Sandra Lamm, VDSS)	IRB_2023-04	10/17/2023	<p>Due to staff illness, the data collection period for both the online and worker-assisted surveys will be extended to 10/31/2023 to allow EAP staff more time to catch up on conducting worker-assisted surveys.</p>

Title / Principal Investigator (PI)	IRB #	Modification Approval Date	Proposed Modifications
Energy Assistance Program (EAP) Cooling and Heating Surveys (PI: Sandra Lamm, VDSS)	IRB_2023-04	11/8/2023	Due to delays in staff onboarding, the survey data collection period for the Cooling Survey will be extended through November 30 to allow EAP staff to conduct worker-assisted survey follow-up with clients.
Energy Assistance Program (EAP) Cooling and Heating Surveys (PI: Sandra Lamm, VDSS)	IRB_2023-04	6/28/2024	<ul style="list-style-type: none"> <li>• Conduct a pilot of a worker-assisted phone interview to replace the online version. Clients will be notified in advance by mail. Workers will enter responses in Qualtrics.</li> <li>• As part of the interview, the worker will ask the client for their permission to enter their case number in the survey response to allow the research team to link program data to the survey response. The interviewer will not be analyzing the data.</li> </ul>
Increasing the tax credit take-up through understanding barriers in tax filing among the VDSS clients (PI: Jiwoo Pierson, VDSS)	IRB_2023-05	12/11/2023	<ul style="list-style-type: none"> <li>• Demographic questions and questions about filing history and intent to file taxes in the upcoming tax year have been removed from the survey. Consent form updated.</li> <li>• Dr. Jeff Price is no longer working at VDSS and has been removed as co-PI on this project.</li> </ul>
Fostering Responsible Parents in Virginia (PI: Mariellen Keely and Taylor Ashe, VDSS)	IRB_2023-11	9/6/2023	<ul style="list-style-type: none"> <li>• Increase the total compensation from \$50 to \$75, and pay the majority of the compensation after the study's mid-way point. The consent form has been amended.</li> <li>• Add a recruitment video to attract more foster youth.</li> <li>• Rather than having coordinators collect demographic information on participants, subjects will be asked for demographic background on the pre-test survey. Subjects are allowed to skip answering the demographic questions except age.</li> </ul>

<b>Title / Principal Investigator (PI)</b>	<b>IRB #</b>	<b>Modification Approval Date</b>	<b>Proposed Modifications</b>
Trauma-Informed Motivational Interviewing Survey (PI: Lauren Weidner, Virginia Commonwealth University, and Tiffany Gardner, VDSS)	IRB_2023-14	10/13/2023	Allow two additional researchers (a student researcher and her faculty supervisor), affiliated with VCU, to have access to de-identified data from four surveys. VCU's CEP-VA will establish a data sharing agreement with Sage.

## APPENDIX D: VDSS IRB MEMBER ROSTER, SFY 2024

<b>Name</b>	<b>Title</b>	<b>Organization</b>	<b>IRB Start Date</b>	<b>Non-Scientist?</b>	<b>Other Area of interest</b>
Jamie Cage, PhD	Assistant Professor	Virginia Commonwealth University	12/13/2021	Yes	Varied (child welfare, public assistance, prison populations, early education)
Christopher Campbell, MBA, MPA	Director of Advocacy and Program Advancement	Virginia Home for Boys and Girls	6/9/2022	No	Child welfare, Disability, Homelessness, Gender diversity, Early child care
Mitzi Fletcher, MSW	Data Governance Manager	VDSS (Research & Planning)	9/1/2023	Yes	Child abuse and neglect; Early child care; Secondary data analysis, Data security/privacy
Peter Gregory, MPA, PhD	Senior Research Associate	Virginia Department of Juvenile Justice	9/1/2023	Yes	Disability, Incarceration, Refugees, Violence prevention
Carolyn Hawley, PhD, CRC	Associate Professor	Virginia Commonwealth University	3/1/2016	Yes	Varied (Children/Youth; Elderly, Incarceration; Abuse); Rehabilitation Counseling, Disability, Resilience, Research
Dev Nair, PhD, MPH	Assistant Commissioner	Virginia Dept. of Behavioral Health and Developmental Services	6/9/2022	Yes	Varied (disability, abuse and neglect)

<b>Name</b>	<b>Title</b>	<b>Organization</b>	<b>IRB Start Date</b>	<b>Non-Scientist?</b>	<b>Other Area of interest</b>
Em Parente, PhD, LCSW	Assistant Director, Policies & Practice	VDSS (Family Services)	9/1/2013	No	Child welfare, gender equity
Timothy Reddish, MSW, Mdiv	Foster Care Program Supervisor	Commonwealth Catholic Charities	6/9/2022	No	Varied (Child and adult abuse, homelessness, refugees, public assistance)
Tamara Temoney-Porter, PhD	Director	Hampton Dept. of Social Services	7/1/2015	No	Varied (child welfare, public assistance, early child care); Public Policy, Human Services
Stephen Wade, MUP	Health Equity Program Manager	VDSS (Community and Volunteer Services)	6/9/2022	No	Varied (disability, incarceration, refugees); Substance use, Housing, Transportation
Gail Jennings, PhD (Chairperson)	Senior Research Associate	VDSS (Research & Planning)	7/1/2012	Yes	Varied; Psychology, Human Services, Research/Evaluation
Aline Jesus Rafi, PhD (IRB Administrator)	Research Associate Senior	VDSS (Research & Planning)	1/30/2023	Yes	Foster care; research, evaluation
Andrew Sell, MBA (IRB Administrator)	Research Associate Senior	VDSS (Research & Planning)	1/3/2023	Yes	Research, evaluation

# APPENDIX E: VDSS IRB MEETING MINUTES (JUNE 25, 2024)

**Date and Time:** June 25, 2024, 3:00 – 3:30 pm

**Location:** **Virtual** (Microsoft Teams)

Meeting ID: 291 419 580 775

Passcode: RegNkc

## Dial in by phone

+1 434-230-0065 (United States); Phone conference ID: 184 601 021#

**Members Present:** Gail Jennings (VDSS, IRB Chairperson); Chris Campbell (VHBG), Mitzi Fletcher (VDSS), Peter Gregory (DJJ), Carolyn Hawley (VCU), Dev Nair (DBHDS), Tim Reddish (CCC), Tamara Temoney-Porter (Hampton DSS), Stephen Wade (VDSS), Aline Jesus Rafi (VDSS, Co-Coordinator), Andrew Sell (VDSS, Co-Coordinator). **ABSENT:** Jamie Cage (VCU), Em Parente (VDSS).

## OLD BUSINESS/ANNOUNCEMENTS:

- Personnel Changes:
  - Robert Arons – new ORP Director (started 11/10/2023). He has not been involved in IRB operations.
  - James Williams – Acting Commissioner (starting April 2024) for the next 12-18 months.
- Reviewed Studies – No full board or expedited reviews this year. A summary of exemption determinations was distributed by email. Compared to FY 2023, the workload (number of reviews) was light.
- Regulatory Updates (Periodic Reviews)
  - 22 VAC 40-890 (Human Subject Research Regulations: 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). The changes were approved by the State Board of Social Services (December 2022), later reviewed by the Department of Planning and Budget, and then sent to SHHR for review. No action has been taken by SHHR for 440+ days. A new periodic review cycle has started. It is out for public comment in the Town Hall.
  - 22 VAC 40-910 (General Provisions for Maintaining and Disclosing Confidential Information...): No proposed changes.
- HRP and Other Training
  - ORP renewed its subscription to CITI for human research protection training last December and recently added a new CITI course (Participant-Centered Informed Consent) developed by OHRP. New course will be available to IRB members and researchers soon. More information is forthcoming.
  - New survey research and design training being developed by ORP. The videorecorded training will be available to DSS employees in the Virginia Learning Center.



The intent is to improve survey design skills and the quality of survey instruments developed by DSS staff.

**FULL BOARD REVIEW:**

None.

**NEW BUSINESS:**

- Designation of a Signatory Official (SO): Beside the head of the Agency (Commissioner), who can serve in this role?
  - The SO approves all agency contracts, including Reliance/Authorization agreements. When registering the IRB and FWA with OHRP, it requires the name of the Signatory Official.
  - At VCU, the SO is typically a Procurement Officer, who is required to complete training. CITI has training designed specifically for signatory officials.
  - ORP will request that the Acting Commissioner be named the Signatory Official for VDSS or otherwise appoint a designee from Procurement. The FWA will be updated.
- Does the VDSS IRB need an Ombudsman? Who should serve in this role?
  - Jeff Price, the previous director for ORP, served as an Ombudsman. It is not known if he took on this role specifically in regards to IRB operations. (BTW Jeff served as a voting member of the IRB and attended meetings to assure a quorum of members).
  - The role of the Ombudsman is to address grievances involving the IRB, which can be brought forth by principal investigators, study participants, etc. if there is a concern about a research project.
  - The contact information for the Ombudsman is listed on consent forms and all notifications to subjects.
  - The Ombudsman is typically appointed from within the IRB or the Office of human research protection (e.g., HRP director).
  - The Governor's Office of Data Governance and Analytics (OGDA) and the VLDS data governance committee and participating agencies were unable to provide any further guidance or information.
  - It was recommended that we contact the state Office of the Attorney General as well as the VDH IRB. The IRB Chair will contact both organizations.
  - During Jeff's tenure as ORP director and Ombudsman, no complaints or grievances were received.

Addendum: At the ORP staff meeting on 6/26/2024, Robert Arons agreed to serve as Ombudsman for the IRB. If it becomes necessary to expand the role to cover the entire agency, we will seek input from ISRM.

- Appointment of HRPP (Human Research Protection Program) Director – Not discussed.
- IRB Management Solution
  - SaaS (online) solution that supports full life cycle management of IRB submissions
  - ORP reviewed several products and particularly preferred one solution above all.

- If cloud-based, the software requires a COVRAMP assessment; may require ORP to issue a Request for Proposal. ORP hopes to purchase a project by the end of next fiscal year.
- Re-Appointments for FY 2025-2026: The Chair thanked IRB members for responding to the poll regarding reappointment to the Board for FY2025-2026. The Commissioner must approve all appointments. The IRB Chair has started the process of obtaining approval. Reappointment letters are likely to be sent to appointees in the next two weeks.

**ADJOURNED TIME:**

The meeting adjourned at 3:20 pm.