

Danny TK Avula MD, MPH Commissioner

September 12, 2023

MEMORANDUM

TO: The Honorable Glenn Youngkin

Governor of Virginia

Members, Virginia General Assembly

FROM: Danny TK Avula MD, MPH

SUBJECT: Annual 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.

DA:kc Attachment

cc: The Honorable John Little, Secretary of Health and Human Resources



ANNUAL REPORT ON HUMAN SUBJECTS RESEARCH

September 2023

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REPORT ON HUMAN SUBJECTS RESEARCH VDSS INSTITUTIONAL REVIEW BOARD SFY2023

EXECUTIVE SUMMARY

REPORT MANDATE

Title 63.2-218. Board to adopt regulations.

The Board shall adopt such regulations, not in conflict with this title, as may be necessary or desirable to carry out the purpose of this title. Before the Board acts on a regulation to be published in the Virginia Register of Regulations pursuant to § 2.2-4007.05, the Board shall examine the potential fiscal impact of such regulation on local boards. For regulations with potential fiscal impact, the Board shall share copies of the fiscal analysis with local boards prior to submission of the regulation to the Department of Planning and Budget for purposes of the economic impact analysis under § 2.2-4007.04. The fiscal impact analysis shall include the projected costs and savings to the local boards to implement or comply with such regulation and, where applicable, sources of potential funds to implement or comply with such regulation.

The Board also may adopt such regulations to authorize local boards to destroy or otherwise dispose of such records as the local boards in their discretion deem are no longer necessary in such offices and that serve no further administrative, historical or financial purpose.

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 22 VAC 40-890 et seq.) statutes. The IRB reviews, approves, and monitors research conducted or authorized by VDSS, local departments of social services (LDSS), 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-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 or interviews. 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 2023 Change in IRB Staffing

The VDSS IRB is overseen by the VDSS Office of Research and Planning (ORP), under the direction of Dr. Jeff Price. Dr. Danny Avula, the VDSS Commissioner, serves as the Signatory

Official for the agency. In addition to her job as a policy research analyst in ORP, Dr. Gail Jennings serves as the Chairperson and is the chief administrator for the VDSS IRB.

There were two noteworthy changes in staffing that impacted IRB operations in SFY 2023. First, due to significant increases in IRB submissions, the ORP Director assigned Dr. Aline Jesus Rafi and Mr. Andrew Sell, both policy research analysts in ORP, to help Dr. Jennings with the increased workload. With additional staffing, the IRB has continued to run smoothly and efficiently.

Second, Dr. Jeff Price, the Director of ORP, who also served as Ombudsman for VDSS since 2013, resigned from VDSS in June 2023 to take a position at another state agency. Recruitment for the ORP director position is underway. In the interim, Dr. Jesus Rafi serves as Acting Director. After the director position is filled, VDSS leadership will determine who should serve as the Ombudsman for the agency.

Change in IRB Membership

Two members of the IRB – Dr. Dhara Amin of the Virginia Department of Juvenile Justice (DJJ) and Dr. Jessica Marcon Zabecki of the Virginia Department of Education (VDOE) -- resigned their positions in the IRB. Dr. Amin, who had been an IRB member since 2018, left in August 2022. Dr. Zabecki, a research analyst at VDOE, joined the IRB in March 2023 but left three months later. The IRB Chair contacted DJJ and VDOE to identify suitable replacements. Both agencies have identified individuals, and their appointments will be made in SFY 2024. For the latter half of SFY 2023, the IRB had ten members plus the IRB Chair (Dr. Jennings), the co-Administrators (Dr. Jesus Rafi and Mr. Sell), and the Agency Ombudsman (Dr. Price). The roster of VDSS IRB members is in Appendix A.

Board Meetings

The VDSS IRB met on October 11, 2022, thus complying with state regulations that the IRB meet at least once yearly. A quorum of members attended the virtual meeting, during which a full board review was conducted. The IRB reconvened on December 2, 2022, to discuss developing clearer guidance about participation of foster children in human research. The minutes of both meetings are in the appendices.

Studies Approved

The VDSS IRB reviewed a total of 35 human subjects research studies – a significant increase from the year before. Procedures determining which type of review is conducted are determined by state and federal codes (e.g., 22 VAC 40-890 and 45 CFR 46). A summary of each study submitted and reviewed by the VDSS IRB in SFY2023 are described in more detail in the appendices. Here is a summary of the number of reviews conducted by the VDSS IRB.

- One study required a **Full Board** review because it potentially posed more than minimal risk to human participants.
- Eleven studies received an **Expedited** review by the IRB Chairperson or by one or more other experienced reviewers designated by the Chair.
- Nine studies underwent an exemption determination and were deemed **Exempt** from most

- federal regulations under 45 CFR 46.
- The Chair (or a designee) approved **Modifications** submitted by ten previously approved studies and **Continuances** of four previously approved studies. Starting in SFY 2023, new studies initially approved under an expedited review procedure do not require a continuing review unless the IRB decides otherwise.

Other Activities

During SFY 2023, the IRB Chairperson initiated the periodic review process for state codes 22 VAC 40-890 (Human Subject Research Regulations) and 22 VAC 40-910 (General Provisions for Maintaining and Disclosing Confidential Information of Public Assistance, Child Support Enforcement, and Social Service Records). The Chair recommended more extensive revisions to 22 VAC 40-890 to bring it in compliance with 2018 changes to the federal code (45 CFR 46). Minor changes were recommended for 22 VAC 40-910. Both chapters are currently at different stages of the fast-track review process.

In addition, the IRB Chairperson and Administrators started and/or completed the following projects:

- Developed clear, more detailed guidance regarding participation of foster children in human subjects research and who may provide informed consent on behalf of foster children.
- Established a new policy requiring principal investigators and their research staff to show evidence of completion of human research protection training.
- Developed a human subjects research decision-making tool for new investigators.
- Investigated ways to modernize the IRB's recordkeeping system and streamline the submission and review processes. We identified at least one IRB management solution on the market.

CONCLUSION

All research approved by the IRB in SFY 2023 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 2024 are as follows:

- Continue to promote <u>Collaborative Institutional Training Initiative (CITI)</u> as a source for human research protection training for DSS staff, IRB members, and new investigators.
- Release the new Human Subjects Research decision-making tool.
- Incorporate information about the IRB in a new survey training video designed for DSS employees.
- Purchase a cloud-based IRB management solution; complete set-up and user training in SFY 2024.
- Add new IRB members to serve the interests of vulnerable populations (e.g., young and school-age children, incarcerated or detained individuals).

REPORT ON HUMAN SUBJECTS RESEARCH VDSS INSTITUTIONAL REVIEW BOARD SFY2023

REPORT MANDATE

Title 63.2-218. Board to adopt regulations.

The Board shall adopt such regulations, not in conflict with this title, as may be necessary or desirable to carry out the purpose of this title. Before the Board acts on a regulation to be published in the Virginia Register of Regulations pursuant to § 2.2-4007.05, the Board shall examine the potential fiscal impact of such regulation on local boards. For regulations with potential fiscal impact, the Board shall share copies of the fiscal analysis with local boards prior to submission of the regulation to the Department of Planning and Budget for purposes of the economic impact analysis under § 2.2-4007.04. The fiscal impact analysis shall include the projected costs and savings to the local boards to implement or comply with such regulation and, where applicable, sources of potential funds to implement or comply with such regulation. The Board also may adopt such regulations to authorize local boards to destroy or otherwise dispose of such records as the local boards in their discretion deem are no longer necessary in such offices and that serve no further administrative, historical or financial purpose.

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 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 employees. The IRB may review human subjects research activities that are proposed, conducted and/or authorized by VDSS, the local departments of social services (LDSS), or VDSS-licensed facilities or contractors when conducting research on behalf of the VDSS.

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 one or more criteria for exemption status (i.e., exemption from most federal requirements under 45 CFR 46)2) is appropriate for expedited review, or 3) requires full board review. Generally, the IRB Chairperson or one or more experienced reviewers conduct 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.

Typically, the VDSS IRB reviews social-behavioral studies, not clinical or animal 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 include: possible violations of subject privacy and loss of confidentiality of sensitive or personally identifiable information; inequitable treatment, including 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.

FUNCTIONS

Federal regulations mandate that research involving human participants must be reviewed and approved by an 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. 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 to 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 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 waive documentation in accordance with federal and state 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. 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 appropriate institutional official.
- 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 ACTIVITIES IN SFY 2023

Federal-Wide Assurance and IRB Registration

Since 2006, VDSS has formally assured the U.S. Department of Health & Human Services (USDHHS) that the state agency will comply with requirements set forth in the Protection of Human Subjects regulations at 45 CFR 46 et seq. Compliance, known as a "federal-wide assurance," is a necessary condition for VDSS to receive federal grants that include human research activities. Among other things, the terms of the assurance require VDSS to submit its studies for review to an internal IRB or rely on an external review board for oversight. The agency's federal-wide assurance (#FWA00010976) with the OHRP was last updated on 4/15/2022; the assurance is effective through 4/15/2027. In addition, the VDSS IRB's registration (#IORG0004422) with OHRP was last updated on 5/5/2022, noting changes in the agency's leadership, the IRB's administration, and the IRB membership. The registration is effective through 5/5/2025.

Change in IRB Staffing

The VDSS Office of Research and Planning (ORP) is responsible for administering the VDSS IRB and ensuring compliance with federal and state regulations regarding human subjects research. The VDSS Commissioner (Dr. Danny Avula) serves as the Signatory Official for any research activities conducted or supported by the agency. Dr. Jeff Price, the ORP Director, serves as the agency's Data Ombudsman and has general oversight over IRB activities. The Ombudsman regularly attends IRB meetings and serves as an alternate voting member if a quorum is not attained. In addition to her job as a policy research analyst in ORP, Dr. Gail Jennings serves as the Chairperson and is the chief administrator for the VDSS IRB. The organizational chart showing the IRB's oversight is in Appendix A.

There were two noteworthy changes in staffing that impacted IRB operations in SFY 2023. First, due to significant increases in IRB submissions and inquiries, the ORP Director assigned Dr. Aline Jesus Rafi and Mr. Andrew Sell, both policy research analysts in ORP, to help Dr. Jennings with the increased workload. Collectively, the IRB administrators are responsible for processing IRB submissions, entering information into the IRB's recordkeeping system, conducting exemption determinations, performing expedited reviews and/or delegating expedited reviews to other IRB members, communicating with principal investigators and board members, updating submission forms, maintaining the IRB web page, and responding to email inquiries sent to the IRB's email address (irb@dss.virginia.gov). The IRB chairperson is responsible for

convening and leading board meetings, conducting votes, and publishing meeting minutes. With additional staffing, the IRB has continued to run smoothly and efficiently and start several high priority projects.

Second, Dr. Price resigned his position as ORP Director in mid-June 2023 to take a position at another state agency. Recruitment for the ORP director position is underway. In the interim, Dr. Jesus Rafi serves as Acting Director. After the director position is filled, VDSS leadership will determine who should fill the role of the Ombudsman for the agency.

Change in IRB Membership

Dr. Dhara Amin of the Virginia Department of Juvenile Justice (DJJ), a long-standing member of the board since 2018, resigned from the VDSS IRB in August 2022. Since then, the IRB has not had a representative from DJJ to serve in her place and represent the interests of incarcerated individuals, including foster youth involved in the juvenile justice system. Recently, DJJ notified the IRB that Dr. Amin's vacant position was filled, and that the new employee is interested in serving on the board. The new appointment will be made in SFY 2024.

Dr. Jessica Marcon Zabecki, a research analyst at the Virginia Department of Education (VDOE), joined the IRB as a new voting member in March 2023. Her research background and role at VDOE was considered an asset when appointing her to the VDSS IRB. However, her tenure with the board was brief. Dr. Zabecki resigned in June 2023 to take a new job outside of the Commonwealth of Virginia. To-date, another suitable candidate has been identified and will be appointed to the board in FY 2024. This new member will represent the interests of children in primary and secondary public schools and children and families who are served by licensed and/or regulated early child care programs.

In addition to the IRB Chair (Dr. Jennings) and the co-Administrators (Dr. Jesus Rafi and Mr. Sell), the IRB had ten (10) voting members during the latter half of SFY 2023. As the agency Ombudsman, Dr. Price served as an alternate voting member. Each member's appointment is effective through June 30, 2024. The VDSS IRB complies with all state and federal human research regulations regarding its composition. The roster of VDSS IRB members for SFY 2023 is in Appendix B.

Board Meetings and Communication

In fulfillment of state regulations, the acting VDSS IRB Chairperson convened its annual meeting of the Board on October 11, 2022. A quorum (11 members) attended the virtual (online) meeting. The main highlights of the meeting were:

- The IRB Chair introduced four new board members (Dr. Dev Nair, Tim Reddish, Christopher Campbell, and Stephen Wade), who were appointed in June 2022.
- The Chair informed board members about new expedited studies and studies that meet exemption criteria during the first half of SFY 2023. The Chair also shared a copy of the FY 2022 annual IRB report to the General Assembly.

• The members held a full board review of a study conducted by Ms. Andrea Poe, a doctoral student from the Shenandoah University School of Health Professions. The study, "Using Play to Cultivate Resilience Within Foster Families: An Occupational Therapy-Based Community Program" (#IRB_2023-03), is described in more detail in Appendix E. The Board agreed to defer a vote on the study until the principal investigator addressed questions and issues raised by the IRB. The meeting minutes are saved in Appendix C.

At the request of one of its members, the Chairperson called a meeting on December 2, 2022, to discuss current policy and practice regarding participation of foster children (aka "wards of the state") in human subjects research. Various research organizations offer different interpretations of state and federal rules about inclusion of foster care children ("wards of the state") in human subjects research and defining who may serve as a "legally authorized representative" and consent on behalf of foster care children. As there is no clear guidance published on the VDSS IRB web page, the meeting was called to determine what the VDSS guidance should be. Several members, particularly Drs. Parente and Cage, Mr. Reddish, and Mr. Campbell, all who serve foster children, shared their viewpoints. The IRB agreed to have a small working group (the IRB co-administrators and Drs. Cage and Parente) draft more detailed guidance, which was approved and posted to the IRB web page in Spring 2023. The meeting minutes are saved in Appendix D.

In addition to conducting board meetings virtually through Microsoft Teams, the IRB administrators created a Teams channel to facilitate communication and file-sharing among its members.

Other IRB Activities

Regulatory Review

Virginia Administrative Code 22 VAC 40-890 (Human Subject Research Regulations) underwent a periodic review in FY 2022-2023. The proposed changes entail clarification of terms and definitions and updating sections of the chapter to better align them with recent changes to the federal regulations (2018 Common Rule). The revisions will provide additional clarity and appropriate flexibility in conducting human subject research reviews. In December 2022, the State Board of Social Services approved the proposed changes. After undergoing review by the Virginia Department of Planning and Budget, the changes are now under review in the Office of the Secretary of Health and Human Resources.

The IRB Chair identified two terms in 22 VAC 40-910 (General Provisions for Maintaining and Disclosing Confidential Information of Public Assistance, Child Support Enforcement, and Social Service Records) that needed to be updated. The Divisions of Benefit Programs, Family Services, and Child Support Enforcement did not foresee a need for more changes to the remainder of the chapter. After posting the regulation in the Town Hall in December 2022 (no

¹ The chapter is being updated to reflect current federal regulations (regarding circumstances under which human subjects research would qualify for either exemption from IRB review or expedited review).

comments were received), the IRB Chair submitted a request for a fast-track review, which the State Board of Social Services approved in April 2023. The proposed changes are not likely to substantially impact the agency or regulated parties. The proposed changes are under review by an assigned attorney in the Virginia Office of the Attorney General.

To comply with the Governor's executive order for regulatory reform, VDSS is conducting a review of all regulations and guidance documents to identify ways regulatory burden can be reduced. ORP has established a baseline for the number of statutory and discretionary requirements contained in both above-mentioned codes.

IRB Policy Development.

As previously described on page 10, the IRB members discussed drafting clear guidance on participation of foster care children and youth in human subjects studies approved by the IRB. Developed by an IRB work group, the new policy ("Guidance on Informed Consent for Children in Foster Care") was reviewed and approved by the full board and published on the VDSS IRB web page.

The IRB administrators also developed a new training requirement policy ("Human Research Protection Training Required for Research Personnel") that went into effect July 1, 2023. Per the new policy, "the principal investigator, other investigators, or any other personnel who are to be engaged in human research (i.e., research personnel) for a study under VDSS IRB review will be required to have completed a valid human research protection (HRP) training before a study may be approved." The principal investigator must show evidence (i.e., certificates of completion) that recent training was completed and is current throughout the term of the study. If HRP training is not available to the investigator and their staff, they may avail themselves of free (at no cost) online training offered by the VDSS IRB. Starting July 1, the new training policy applies to new studies requesting an IRB review and to already approved studies that request a continuation.

IRB Human Subjects Research Decision-Making Tool

The IRB chair frequently responds to inquiries from VDSS employees about whether or not their projects fall within the category of "human subject research". Often the project does not qualify as either research or involving human subjects (e.g., QA/QI project). Adapting an existing tool developed by the University of Loyola-Maryland, the IRB administrators created an online questionnaire in Qualtrics that leads the user through a series of decision points and concludes with a determination the study in question either qualifies as human research or does not meet the criteria. The tool will aid new investigators in determining whether or not they need to engage with the IRB. As of June 30, the tool was undergoing review and testing by VDSS staff.

IRB Management Solution

Currently, the IRB administrators use a stand-alone Microsoft Access database to enter information about each IRB submission, from initial review to study closure. The database is not accessible to investigators and IRB members. Data entry is time-consuming and inefficient. As

part of the agency's digital transformation efforts, the IRB will begin modernizing its IRB submission and review processes. A new solution will confer several benefits including: 1) efficient submission and review processes through a user-friendly platform, 2) enhanced compliance with federal and state regulations, and 3) improved transparency and accountability.

In the latter half of the fiscal year, the IRB administrators considered several solutions, including reviewing existing products on the market. Following product demonstrations by three vendors, the IRB concluded that the best option was to purchase a subscription to a SaaS (software as a service) solution that provides full lifecycle management of IRB submissions rather than build a system in-house. The solution or product under consideration will provide many beneficial features including automated workflows, reports and dashboards, customization of forms (screens) and letter templates, meeting management, integration with CITI to verify HRP training for investigators, and password-protected access for stakeholders (researchers, IRB administrators, and IRB members). In early SFY 2024, the IRB will start completing the paperwork for the IT security review process and procurement.

Consultation to VDOE

In 2021, the Virginia Department of Education started the process of establishing its own human research review committee. Early on, the director of the VDOE Office of Research consulted with the Office of Research and Planning and the VDSS IRB about policies and best practices, state regulations, and infrastructure support for developing an institutional review board. By the end of SFY 2023, VDOE has established an IRB and one of the ORP staff has volunteered to serve on the VDOE board.

Approved Studies

Compared to SFY 2022, the IRB reviewed almost triple the number of IRB submissions (including initial reviews, exemption determinations, modifications, and continuations) in SFY 2023 (35 versus 13).

- One (1) study underwent a **Full Board** review in SFY 2023. 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.
- Eleven (11) new projects 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.
- Ten (10) previously approved studies requested approval of **Modification**(s) to their protocols. Four (4) studies required a **Continuing Review** of their studies. 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.
- Nine (9) research projects underwent Exemption Reviews and were deemed **Exempt** from most federal laws, under conditions described in 45 CFR 46. The IRB Chairperson

or an Administrator may conduct Exemption Determinations, reviews of Modifications, and Continuing Reviews.

Refer to the Appendices for a brief description of each study, which are listed by type of IRB review received: Full Board reviews in Appendix E, Expedited reviews in Appendix F, Exemption determinations in Appendix G, and Modification and/or Continuation reviews for previously approved studies in Appendix H.

Five previously approved studies closed in SFY 2023.

"Vision 21: Linking Systems of Care (LSC) Listening Tour" (IRB_2018-12). PI(s): Anna Cody and Kimberly Scott-Barbarji, Virginia Department of Social Services, Division of Family Services. Approved on 5/24/2018. Closed on 10/31/2022 with no adverse events. Findings are available at: A copy of the report is available on the Virginia HEALS website at: https://virginiaheals.com/wp-content/uploads/2019/06/listening_tour_report_FINAL.pdf.

"The Correlation between Secondary Traumatic Stress, Burnout, and Employee Satisfaction and Employee Engagement amongst Residential Facility Employees in Children's Residential Facilities" (IRB_2020-02). PI(s): Tiffani White-Simeonides (doctoral student), Grand Canyon University. Approved on 9/24/2019. Closed on 2/1/2023 with no adverse events.

"VDSS LGBTQ+ Training Evaluation" (IRB_2021-01). PI(s): John Ruane and Michaela Dench, Virginia Commonwealth University School of Social Work. Approved on 1/5/2021. Closed on 11/3/2022 with no adverse events.

"The Perceptions of Integrating Digital Literacy with TANF Work Programs to Empower Participants for Economic Self-Sufficiency" (IRB_2022-12). PI(s): Debra Jones (doctoral student), Regent University. Approved on 4/14/2022. Closed on 3/14/2023 with no adverse events.

"Using Play to Cultivate Resilience Within Foster Families: An Occupational Therapy-Based Community Program" (IRB_2023-03). PI(s): Andrea Poe (doctoral student), Shenandoah University School of Health Professions. Approved on 11/7/2022. Closed on 4/19/2023 with no adverse events.

All studies listed above have a brief description of their findings published on the VDSS IRB web page (https://www.dss.virginia.gov/irb/results.cgi).

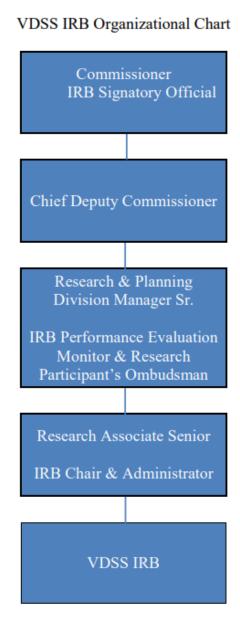
CONCLUSION

All research approved by the IRB in SFY 2023 satisfied the regulatory definition of minimal risk and involved activities like surveys, interviews, training evaluation, evaluation of delivery of services and benefit programs, and analysis of administrative data.

The following activities are priorities for SFY 2024:

- Promote <u>Collaborative Institutional Training Initiative (CITI)</u> as a source for human research protection training to VDSS and LDSS staff who are involved in departmental research; continue to provide this training opportunity to new and continuing IRB members. One broadcast notification has already been sent in Spring 2023.
- Launch the new Human Subject Research decision-making tool and promote its usage to VDSS and LDSS employees through intranet broadcasts. Publish a link to the Qualtrics questionnaire on the IRB web page.
- Incorporate information about the role and function of the IRB into a new survey training video for VDSS and LDSS employees. The video will be saved in the COV Learning Center.
- Obtain approval for purchasing a cloud-based IRB management solution; ensure that the platform meets agency and state security requirements. Purchase an annual subscription, set up the platform, and provide training to end users.
- Ensure that the VDSS Commissioner appoints new members representing DJJ and VDOE, with their terms starting in early SFY 2024.
- Make updates to the content of the <u>VDSS IRB website</u>, as necessary. In FY 2024-2025, VDSS Public Affairs is planning to redesign and revamp its public-facing web site to make it more accessible and user-friendly for content editors and end-users. The IRB intends to improve the layout and content of its web pages to improve accessibility.

Appendix A: VDSS IRB Organizational Chart (Last modified 8/29/2016)



Appendix B: VDSS IRB Membership for SFY 2023 (Last modified 3/31/2023)

| IRB Role | Name | Agency | Title |
|-----------------------|-----------------------------------|---|---|
| Chair & Administrator | Gail C. Jennings, PhD | VDSS, Office of Research and Planning | Senior Research Associate |
| Co-Administrator | Aline Jesus Rafi, PhD | VDSS, Office of Research and Planning | Senior Research Associate |
| Co-Administrator | Andrew Sell, MBA | VDSS, Office of Research and Planning | Senior Research Associate |
| Member | Jamie Cage, PhD | Virginia Commonwealth University, School of Social Work | Assistant Professor |
| Member | Christopher R. Campbell, MBA, MPA | Virginia Home for Boys and Girls, Advocacy and Program Advancement | Director |
| Member | Mary Disse | VDSS, Division of Information Technology Systems | Project Manager |
| Member | Carolyn Hawley, PhD, CRC | Virginia Commonwealth University, Department of Rehabilitation Counseling | Associate Professor |
| Member | Dev Nair, PhD, MPH | Virginia Department of Behavioral Health and Developmental Services | Assistant Commissioner |
| Member | Em Parente, PhD, MSW, LCSW | VDSS, Division of Family Services | Assistant Director, Policies & Practice |
| Member | Timothy Reddish, MSW, MDiv | Commonwealth Catholic Charities | Program Supervisor |
| Member | Tamara Temoney, PhD | Hampton Department of Social Services | Agency Director |
| Member | Stephen Wade, MUP | VDSS, Community and Volunteer Services | Health Equity Project Manager |
| Member | Jessica Marcon Zabecki, PhD | Virginia Department of Education, Office of Research | Research Analyst |
| Ombudsman; Alternate | Jeff Price, PhD | VDSS, Office of Research and Planning | Division Director |

Appendix C: VDSS IRB Board Meeting Minutes – 10/11/2022

Date and Time: 10/11/2022; 3:00-4:00 pm

Location: Virtual (Microsoft Teams: Click here to join the meeting

Meeting ID: 267 340 654 240

Passcode: WizZwE

Members Present: Gail Jennings (VDSS IRB Chairperson); Carolyn Hawley (VCU), Jamie Cage

(VCU), Chris Campbell (VHBG), Dev Nair (DBHDS), Mary Disse (VDSS), Em Parente (VDSS), Jeff Price (VDSS; Alternate), Tim Reddish (CCC), Tamara

Temoney-Porter (Hampton DSS), Stephen Wade (VDSS)

The Chair reminds all board members to recuse themselves from deliberation and voting on any study submitted to the IRB in which they have a potential or perceived conflict of interest. This includes, but is not limited to: service as a principal investigator, co-principal investigator, sub-investigator: receiving funding from the study; serving in a supervisory or subordinate role with the principal investigator of the study; serving as a mentor/trainee relationship with the principal investigator; a family member of the principal investigator; working relationship for grants awarded by VDSS or a LDSS.

OLD BUSINESS/ANNOUNCEMENTS:

Introduction of new members, effective June 2022: Dr. Dev Nair (Department of Behavioral and Human Services); Chris Campbell (Virginia Home for Boys and Girls); Tim Reddish (Commonwealth Catholic Charities); and Stephen Wade (VDSS, Community and Volunteer Services).

Dr. Jennifer Piver-Renna (Virginia Department of Social Services) and Dr. Dhara Amin (Virginia Department of Juvenile Justice) both resigned their positions and membership in the IRB.

FULL BOARD REVIEW:

The IRB will conduct a full board review of IRB Study #2023-03 ("Using Play to Cultivate Resilience Within Foster Families: An Occupational Therapy-Based Community Program"; PI: Andrea Poe, doctoral student at Shenandoah University School of Health Professions).

- Refer to "Summary of Foster Care Family Resiliency Play Therapy Training"
- Commonwealth of Virginia Laws Relevant to Human Subjects Research and Informed Consent – available on the VDSS IRB web page

Appendix A will provide details about the discussion and study.

NEW BUSINESS:

None.

ADJOURNED TIME:

The meeting adjourned at 3:47 pm.

Full Board Review

Study Title: Using Play to Cultivate Resilience Within Foster Families: An Occupational Therapy-

Based Community Program

VDSS IRB # 2023-03 Sponsor/Funder: N/A

Investigator: Andrea Poe (Shenandoah University School of Health Professions doctoral student)

DISCUSSION & QUESTIONS:

- 1. According to <u>Virginia code and regulations</u> and also based on interpretation of the administrative code by the state Office of the Attorney General, local departments of social services in Virginia are not permitted to serve as legally authorized representatives (LARs) for children in foster care in regards to consenting to participation in human subject research. (Furthermore, the foster parents are also not permitted to consent for the child in regards to research participation.) Unless the PI obtains parental consent from the biological (birth) parents who have not terminated their parental rights (TPR), youth in foster care will not be allowed to participate in this study, in any capacity. We do not have an alternative process in place to have a Guardian ad Litem (GAL) or other advocate represent the child's interests.
- 2. This may be a moot point (see #1 above): Is the study recruiting any youth who are in treatment foster care (TFC) homes and managed by private providers (e.g., UMFS, Embrace, Hopetree)?
 - o If yes, what level of VEMAT (Virginia Enhanced Maintenance Assessment Tool) services are they receiving? For children and youth who are receiving high level services, participation in the study may be an undue burden to both foster child and foster parents. We strongly recommend that the study consider excluding foster families caring for children who are in TFC homes and receiving VEMAT services.
 - o If the PI intends to recruit a broader pool of foster families, including families who work with a private provider (e.g., licensed child placing agency, or LCPA), the study may have to go through another level of review and scrutiny by the LCPA. Most LCPA's have policies and procedures regarding research; some have established human research review committees. This applies to research involving children and adults. As it stands, Virginia law and regulations do not permit any local department, LCPA or other private provider to consent on behalf of the children. However, even if the study is recruiting adults only, the PI would have to submit their study for review to the LCPA's research review committee if families are managed by a private provider.
- 3. On the Recruitment Foster Parent Info form, participants were asked about preferred week day and time as well as mode of delivery for the training. The PI needs to explain how the participant's time and mode preferences will be used in scheduling and delivering the training. Is it the PI's intent to deliver a group training or individualized training sessions based on each subject's preference? Given that the study is recruiting up to 16 adults, it doesn't seem feasible that the study will achieve any consensus within the group on when and how to deliver the training. Also, the training venue (whether in-person, virtual, or hybrid) may have an impact on training outcomes. How will the PI account for time, place, and mode in the study design and analysis?
- 4. The Board strongly encourages the PI to increase the study's sample size to achieve generalizable results. We understand if this is not always feasible given the study's time constraints. The study would be considered exploratory and the sample size would be a

- limitation noted in the study. Also, with such a small sample, this increases the chances that parent responses will be easily identifiable.
- 5. On page 3 of the Adult Informed Consent form, it's noted that the Family Services Supervisor will be reviewing the recorded sessions afterwards ("Voice or video recordings will only be viewed by the principal investigator and supervising family services manager and will be permanently deleted following completion of this study."). On the Request for Initial Review form, it's noted that the Supervisor (or site mentor) may view the training to document that the training sessions occurred. The PI needs to explain why it's necessary for the Supervisor (site mentor) to observe the recordings and what the Supervisor will do with information gathered from the recordings. Are there alternatives ways to gather evidence that study activities occurred? Even if the site mentor listens to a voice recording only, she may be able to identify individual participants. That removes anonymity from the study. Furthermore, awareness that the training may be observed by the Supervisor/site mentor at a later point may influence participants' willingness to participate and/or speak openly and honestly about their interactions with the foster child. From the Supervisor's perspective, sensitive information disclosed by the foster parent during the training may influence the local department's decision to have the family continue to receive foster care placements.
- 6. Although this may be a moot point (see #1), the Board wants to know the PI's rationale for asking the child respondent to name their foster parents on the child survey. The PI has not provided a reason in any of the documents submitted.
- 7. The Board wants to know the PI's rationale for asking the foster parents to provide the names of all children (foster, biological, adoptive) living in the foster parent's home on the Recruitment Foster Parent Info form (items 5 and 6). Note: Other children living in the home are not participants in this study. The PI has not described what she intends to do with this information.
- 8. The Board wants to know the PI's rationale for collecting the parent respondent's name on the Parenting Survey. In this situation, the survey responses will not be anonymous. Knowing that they are identifying themselves, respondents may not be truthful in answering survey questions, particularly those that are sensitive. Note: Even if the respondent can skip that name question, the respondent may feel obligated to answer. The Board recommends that the PI remove this question in the Parenting Survey under there is a valid reason for collecting this information.
- 9. The survey for youth is age-appropriate, written at a basic level for children ages 7 and older.
- 10. Some Board members expressed concerns about using Google Forms for transmitting sensitive information. They questioned if the university's Google platform was a secure site. The PI is asked to describe the security measures being taken to minimize the risk of accidental disclosure involving information (e.g., names on consent forms, survey responses) stored and transmitted using the Google platform.
- 11. The Board did not express any concerns about the questionnaire or the training posing more than minimal risk to participants, such as triggering trauma.
- 12. Although a moot point (see #1), the Board did not express any concerns about storing consent/assent forms in the foster child's administrative record.
- 13. Regarding the circumstances under which the participant can or should withdraw from the study, the PI is asked to explain what happens to the foster parents' participation in the study if the foster care placement disrupts.
- 14. On page 3 of the Adult Informed Consent form, under Compensation, one of the numbered bullet points ("The approximate number of participants involved in the study is 2 to families") needs to be corrected before it is sent to participants.
- 15. If the foster parent discloses information during the training that may be incriminating (e.g., suggests potential abuse or neglect), what will the PI do with this information? The PI (or trainer) is obligated to report these statements to CPS. Furthermore, the local department can act on certain information if it suggests that the foster parents should not

- continue receiving placements. Participants should be made aware of these exceptions to the confidentiality clause through the Consent Form. The Chairperson asks the PI to consult with Frederick County DSS about the language she should use in the Consent Form.
- 16. The foster parent survey questions should be designed to factor in the youth's current placement and adoption goal. For instance, for youth who have a goal to reunify with their biological parents or a goal to emancipate, the foster parent-foster child relationship (interpersonal dynamics) may be different than for foster family situations. Both foster parent and foster child may have different expectations of what they get out of the training. Is the Pl considering the child's placement and goal when recruiting participants in the study and/or designing the foster parent survey?

Because of the numerous issues raised by the Board members re: this submission, the Board agreed to defer voting until the PI addresses certain questions. The PI was given two weeks to respond by email to the IRB Chairperson. Depending on the PI's responses to the questions and concerns, the Board Chairperson may decide to conduct an expedited review, reconvene the Board for a full board review, or electronically poll Board members on whether the study should be approved.

DECISION AND VOTING:

| DECISION | AND VOTING | • | | |
|-------------------------------|--|---|------------------------|--|
| Present | Scientist (S) Non- scientist (N) | IRB Member | | In person (I) Teleconference (TC) Telephone (TP) |
| \square | S | Gail Jennings, PhD (C | chairperson) | тс |
| \boxtimes | S | Jamie Cage, PhD (VC | U) | тс |
| \boxtimes | N | Christopher Campbell | , MBA, MPA | тс |
| \boxtimes | N | Disse, Mary, B.A. (VD | SS) | тс |
| \boxtimes | S | Hawley, Carolyn, PhD | , CRC (VCU) | TC |
| \square | S | Nair, Dev, PhD (DBHD | Nair, Dev, PhD (DBHDS) | |
| | S | Em Parente, PhD, MSW, LCSW (VDSS) | | тс |
| \boxtimes | N | Tim Reddish, MSW, MDiv (Commonweath Catholic Charities) | | тс |
| \boxtimes | S | Jeff Price, PhD (VDSS; Ombudsman; Alternate) | | тс |
| \square | S | Temoney-Porter, Tamara, PhD (Hampton DSS) | | тс |
| \square | N | Stephen Wade, MUP (VDSS) | | тс |
| Additional Participants: Name | | Role during the meeting: | | |
| N/A | | | | |
| | | | | |

Addendum: The PI's response to the IRB's questions and recommendations were received on 10/28/2022. The PI submitted a revised copy of the study protocol, the Parent Info Form, and the

Parent Pre/Post Survey Form. A significant change is that foster youth will not be asked to participate in the study. This reduces the risk level of the study. Other changes include:

- Families with children receiving VEMAT services will be excluded.
- In order to maintain confidentiality, the Parent Info form no longer requests the names of the youth in the foster parent's home.
- The Parent Consent form indicates that if the parent discloses any information during the training sessions that suggest possible harm to the children in the home or self, the investigator will report this information to appropriate authorities.
- The Pre/Post survey will request an assigned Study ID in lieu of the respondent's name, plus ask about the child's current placement type and permanency goal.
- The Family Services Supervisor (serving as the Capstone project site mentor) will not have access to the recorded sessions.

The Chair invited further feedback from the IRB members by email. A discussion ensued about the wording of a new question on the Parent Pre/Post Survey ("What options best describe your permanency goal for your foster child/children?"). One member thought the phrasing would result in different interpretations. Another member wanted the question to reflect the permanency goal that was court-approved. Another member indicated that some children who recently were placed in a foster home may not yet have an approved goal.

After discussing possible ways to re-phrase the question (e.g., "What options best describe the court-approved permanency goal for the foster child/children in your home?", "What is the foster care goal (sometimes called "permanency goal") for the foster child/children in your home? These goals may or may have been approved yet by the court."), the Chair requested that a few of the members work together to come up with recommendations for the wording of the question. All agreed that the response options should include: Reunification (with parent or prior custodian), Custody transfer to relative, and Adoption. The question posed by the Chair is if children with no approved goal should have the option "Do not have an approved goal".

The Chair (Gail Jennings) proposed a motion to vote to approve the study with revisions. See wording of the motion presented below. The motion was seconded by Carolyn Hawley. The vote took place electronically via an email poll. Members were given a deadline of 11/7/2022 to respond.

Motion: Approve #IRB_2023-03 ("Using Play to Cultivate Resilience Within Foster Families: An Occupational Therapy-Based Community Program"; PI: Andrea Poe, Shenandoah University) with revisions described in the PI's resubmission (received 10/31/2022) as well as rewording of question #3 on the Parent Pre/Post Survey.

A motion to approve the study with revisions was passed 9-0 (1 member absent, no abstentions) on 11/7/2022. Tim Reddish, Tamara Temoney-Porter, and Em Parente will be asked to provide suggestions on appropriate wording for the question and response options.

Appendix D: VDSS IRB Board Meeting Minutes – 12/2/2022

Date and Time: 12/2/2022; 1:00-2:00 pm

Location: Virtual (Microsoft Teams: Click here to join the meeting

Meeting ID: 211 019 712 786

Passcode: Ea2nsp

Members Present: Gail Jennings (VDSS, IRB Chairperson); Carolyn Hawley (VCU), , Chris

Campbell (VHBG), Dev Nair (DBHDS), Tim Reddish (CCC), Stephen Wade (VDSS), Jamie Cage (VCU), Tamara Temoney-Porter (Hampton DSS), Em Parente (VDSS), Andrew Sell (VDSS, Co-Coordinator) **ABSENT:** Mary

Disse (VDSS), Jeff Price (VDSS; Alternate).

The Chair reminds all board members to recuse themselves from deliberation and voting on any study submitted to the IRB in which they have a potential or perceived conflict of interest. This includes, but is not limited to: service as a principal investigator, co-principal investigator, sub-investigator: receiving funding from the study; serving in a supervisory or subordinate role with the principal investigator of the study; serving as a mentor/trainee relationship with the principal investigator; a family member of the principal investigator; working relationship for grants awarded by VDSS or a LDSS.

OLD BUSINESS/ANNOUNCEMENTS:

Introduction of Andrew Sell (VDSS, Office of Research and Planning) as a new member and co-Coordinator. Andrew will assist the Chair, Dr. Gail Jennings, with administrative duties (e.g., submission reviews, coordinate IRB meetings, update guidance documents and forms on the IRB web page, prepare annual reports and regulatory review documents).

FULL BOARD REVIEW:

None.

NEW BUSINESS:

Discuss circumstances under which children in foster care can participate in human subjects research and who may consent on behalf of children in foster care. Refer to the Code of Virginia, federal regulations and additional resources listed below.

22 VAC 40-890-10 (Human Subject Research Regulation - Definitions): https://law.lis.virginia.gov/admincode/title22/agency40/chapter890/section10/

22 VAC 40-910-10 (General Provisions for Maintaining and Disclosing Confidential Information of Public Assistance, Child Support Enforcement, and Social Services Record - Definitions): https://law.lis.virginia.gov/admincode/title22/agency40/chapter910/section10/

Code of Virginia 32.1-162.16 (Human Research – Definitions): https://law.lis.virginia.gov/vacode/title32.1/chapter5.1/section32.1-162.16/

U.S. Office for Human Research Protection, DHHS - https://www.hhs.gov/ohrp/regulations-and-policy/quidance/fag/children-research/index.html

University of Pittsburg Human Research Protection Office - https://www.hrpo.pitt.edu/policies-and-procedures/research-involving-children

University of Virginia Human Research Protection Program - <a href="https://research.virginia.edu/irb-https:

University of Virginia Human Research Protection Program (Wards of the State) - https://research.virginia.edu/irb-hsr/wards-state

MEETING DISCUSSION SUMMARY

Introductions

Andrew Sell was introduced by Gail as a new member of the IRB. He will help Gail with the administrative duties of the chair and coordinator. Each board member present introduced themselves as well.

Discussion Topic

The meeting was called to provide clarification on what VDSS IRB policy should be regarding foster care children participation in research as there is not clear guidance on the website for researchers, especially as it relates to who is authorized to consent on behalf of a minor. Different research organizations have interpreted what is allowable for who can provide consent for foster care youth to participate in research.

Background

Jamie provided background on her previous experience engaging with foster care youth in her research and working with local agencies while in Cleveland, Ohio. She knew engaging youth in foster care and research was very different in Virginia. She met with the Virginia Commonwealth University (VCU) IRB to make sure her research proposal was safeguarded around consent and get their interpretation of Virginia Code. The VCU's IRB interpretation was that local departments could act as legally authorized representatives (LARs) as long as the research was not funded by VDSS. VCU's IRB also interpreted that if a youth was in an out-of-home placement, then the foster parent could consent. She knew that the latter interpretation was not accurate. Because some university IRBs are interpreting Code differently than the VDSS's IRB would, she brought this issue to Gail's attention. She thought it would be beneficial for the VDSS IRB to provide clear guidelines to universities and external agencies so that everyone is on the same page in understanding the guidelines and regulations.

Consent When Parental Rights Have Been Terminated

Gail referenced federal and state regulations that indicate researchers must get consent from the parent or guardian when available. However, it is not clear to researchers what happens in the situation where the parent's or guardian's rights are terminated (TPR).

Em discussed consent practice when it is relates to medical decision-making and Individualized Education Programs (IEPs) and who is authorized to give permission for foster care children when parents still have parental rights. VDSS guidance to local departments is that the foster care worker <u>cannot</u> sign or authorize non-emergency medical treatment that a parent might object to when a parent still has parental rights but is either unavailable or unwilling to give consent. Schools have the same rules related to IEPs. Instead, the mechanism is for the local department to go to the court to ask a judge to make a determination about whether the medical treatment is in the child's best interest. It is a cumbersome process, but sometimes necessary. But more often the local agency tries to work with the family to help them understand why giving consent is in the best interest of the child.

For some children in care, there is a period of time between when parental rights have been terminated and an adoption agreement is in place -- I.e., an adoptive family has been identified and an adoption agreement signed. Adoption finalization by the courts is the last step in the process. The practice has been to let adoptive parents – who have made a permanent commitment to that child and would be that child's parents legally as soon as the court order is issued – make decisions for that child in the interim period.

It is less clear what is done for TPR children who have no adoptive family identified. There are some children who are in that position for an extended period of time – where they do not have a parent with legal parental rights and they do not have an adoptive parent. Em felt strongly that when there is a child with a goal of return home (reunification), the parents should be actively involved, and, if they continue to have parental rights, the local departments should not be consenting for the child to participate in research. The parents need to be consulted, which is extremely awkward since the department cannot give the researcher the contact information for the parent. The question about what happens when there is no parent with parental rights and no adoptive parent identified is a gray area.

Tamara discussed the situation when a child has no parent with parental rights and no adoptive parent identified. With children in that category, the local department would make the decisions regarding signing IEPs, medical consent, etc. because there is nobody else to default to. It is a gray area, particularly regarding research. From a local department perspective, she (as a Division Director) would be hesitant to agree to research because you never know what the outcome could be for the child, especially if it is a type of study that would be potentially harmful. If there was no parent to consent, she would not support or sign off on [the child participating in the study].

Em brought up additional concerns about the risk of conflicts of interest when a local department was consenting for foster care children for some reason other than what is in the best interest of the child. While she did not think it would actually happen, there could still be the appearance that the local department is using their authority inappropriately with regard to very vulnerable children. Parents with [parental] rights should be deferred to and it is a concerning position for a local department to authorize research for children in their care. Tamara agreed with these concerns. And if a parent still has parental rights, it is the parents' decision to make that call.

Other Possible Legally Authorized Representatives for TPR Children

Gail asked if anyone knew what percentage of children were in foster care who have TPR and do not have an adoption agreement signed, what she called a 'limbo' category. Em gave a "very rough" estimate that about 20%-25% of all exits from foster care are to adoption. Gail mentioned that it seems that local agencies are reluctant to act as a guardian or legal representative for the child in this situation. Then she asked whether there is a neutral third party, external to the agency, that could serve as a legally authorized representative and who would that person or entity be.

Tamara mentioned that [the LDSS] would want to know the purpose of the research and what the benefit [to the child and local agency] would be, especially if local agencies are taking extensive measures (outside of what is normally done) to obtain consent for the child to engage in this type of research. Gail added that the principal investigator would have to describe the research purpose and potential benefits of the research.

Em did not know who the person would be (regarding any other legally authorized representatives). There are foster care children who have a Guardian ad Litem (GAL) – attorneys appointed to represent their best interests in the foster care court process. Those attorneys are not answerable to VDSS and their role is described or prescribed by the court process. Em did not know whether the GALs would have any interest in [taking on the responsibility for consenting for the child with no parent or guardian]. When decisions do have to be made (e.g., medical issue) for a foster care child in this group, they do involve the GALs. When they go to court to get a final decision from a judge, they might involve a GAL, but it is very rare. The GAL's role is not exactly prescribed by their role relative to the court process. Many of them do it because they care about the child. Em did not have any sense as to whether a GAL would see [making consent decisions about research participation] as part of their role as a GAL. Tamara agreed. The GAL may not have extensive contact with and knowledge about the child. Even though logically that would be your choice, she did not think it would they would be the best to make that decision either from a practical standpoint.

Gail then asked if Chris or Tim had thoughts on the matter or experience in this area.

Private Provider Perspective

Christopher discussed his experience within a private provider organization which primarily works with youth in the Virginia foster care system. It is often difficult to get consent from parents (TPR or not) when it comes to [signing off on IEPs] in a private day school. It is a cumbersome process to try to get [medical treatment] like wisdom teeth extraction or vaccinations. He reached out to DSS to ask about vaccines and was told that it might be the local DSS [authority] – not DSS [case worker], and maybe not the LDSS director. His organization decided to just wait because his organization saw it as a necessary precaution for [children in] congregate (group) care environment. People in the general public argued whether it was a necessary precaution, and his organization was a smaller group within a smaller group. Christopher also worked in United Methodist Family Services for years which had its own IRB. Like his current organization, each has their own policies around whether the youth in [their]

care who has a placement agreement can participate in research – their own research – or their own fundraising events. Christopher was glad this topic was brought forward because he has been trying to think of a time when he would say it is okay to have this child in research, considering layers of [bureaucracy for so few children]. So it would not be fruitful to go through the process. It has been very difficult from a private provider's [viewpoint] to even get the things done that they think are necessary – research would be a tertiary consideration, it would be another layer.

No Current Consent Mechanism within VDSS for TPR Children

Gail mentioned that we were looking to the Division of Family Services for guidance on this and it sounds like we do not have a mechanism in place to get consent from the local agency when parents' rights were terminated for a child. Gail asked for further thoughts from Em or Tamara.

Em mentioned they valued youth input into their own policy decisions about [serving youth in foster care programs]. However, they collect that information through program evaluations that are generally exempt from the IRB process. They do not collect identifying [personally identifiable] information. They run youth conferences regularly for foster care children. At these conferences, there are sometimes survey stations where children can provide this kind of information while not collecting identifying information, and "table talks" where [Em] stands up in front of the room and asks children to write done on pieces of paper the things DSS should be working on. Information is collected but not as research because of all these barriers around consent.

They still do not have a mechanism. Schools have a mechanism for establishing a LAR for signing IEPs but it is a lengthy and cumbersome process, as Christopher noted. Local [public schools] have to send the IEP out to parent three times to give the parent the opportunity to be involved in the IEP process before they can establish a LAR to sign the IEP. But DSS does not have a similar process [for obtaining consent to participate in research]. The IRB could make a recommendation that we explore how to go about doing such a thing. Em is not saying that the IRB should definitely do that but it is something the IRB could do because it is a gap in the current regulation and actual practice around consent. Em asked Gail about a recent study where [the PI requested] to get consent from the [foster parent] for the child to be able to participate, but then the researcher dropped [requesting foster youth to participate]. Gail explained that the last study reviewed, the researcher dropped the whole piece about collecting data from youth in foster homes. Em could not recall if there was another study where somebody tried to get consent from parents. If [the researcher] included children in the protocol, [the VDSS IRB] required that the child's parents, biological parents or guardian be available to consent. TPR children were not allowed to participate. But that was several years ago.

Advocates for Foster Care Children Participating in Research

Gail asked for Dev's thoughts. Dev discussed that his reading of OHRP guidance referenced needing to appoint an advocate for a child that is participating in research to look for their

needs. He was not sure if it was for any research or just research determined to be high risk. [Risk level] may be another consideration for [the VDSS IRB].

TPR Children: Balancing Benefits of Prospective Research with Concerns about Exploitation

Gail asked for Stephen's thoughts. Stephen thought it sounded like this research, from a practical perspective, would be extremely difficult. From a macro perspective, it seems either -- with Jamie's proposal or just in general -- we would like research to be done to improve this subpopulation. He wondered what other states do. He completely understands the practical realities and is also concerned about trying to get [parents of foster kids] to consent as a significant barrier. But the question of how do we do research to improve this population seems to be a significant, outstanding question that we should discuss.

Gail noted that Dev mentioned the risk level of the study. She then asked whether that consideration would make a difference. Would we allow it in low-risk studies but if it comes to a study that has more than minimal risk we would need an advocate for the child?

Em responded that she would defer to Tamara but she did not think the local departments would want to give consent. Tamara also responded, speaking for herself, but she did not think it would make a difference regarding risk level. Em added that it is just awkward.

Tim asked whether they were saying this from liability [standpoint] or based on precedent. Em responded that it is less about actual liability and more about "appearance". Tamara agreed. It was about "perception". There was already the thought that [the local agencies] are not taking good care of the children and that we are not doing what is in their best interest. All that would be needed was one advocacy group to say, "Now they're doing research on these youth." Even though it could be something that overall will benefit the population, particularly when it is about education and support. If you look at the perception of what will be out there, it is just not worth the risk.

Gail asked Andrew if he had any guidance to add. He responded that it sounds like we are saying it is allowable but whether or not, in practice, local agencies and workers are willing to do that. He asked whether sample size would play any role in whether we would approve it. Tamara responded that that would not make a difference to [her agency].

Em added it is again about the perception. The public already thinks – as a gross overgeneralization – there is a whole abolish child welfare, just like abolish the police. What is our role? We have authority over these families and children already. That is power based and then we are going to use our position to benefit us rather than the children and families that we are serving or benefit someone else – an organization, a corporation – rather than the kids and families we are serving. It is a place that we want to avoid being in. In all circumstances, we want to try to avoid using power when there is an alternative and in this case parents can consent for their children. It is awkward, it is inconvenient, we do not have a good mechanism for it, but whenever there is a parent, the parent should be in the position to consent. Then maybe we look at what are the options for situations where there is not a clear parent who can give that consent. Her concern is that if two different consent mechanisms are created we are

going to do a lot of research only with TPR children and what might that look like? The most vulnerable children the ones you do not have any legal parents to advocate for them then become the ones we do all the research on.

Dev added that an alternative could be to require that there is parental consent and those children that do not have parents to consent would not be in the research. We could say it is different from medical treatment that is essential for the child. This is not essential for the child. But then the other potential issue is that we have no research on those most vulnerable children. Em agreed.

Gail mentioned two exceptions: emancipated minors and youth who turn 18 during the course of the research. They would be eligible to consent for themselves. Em agreed and added that she frequently recommends that foster care population researchers consider the 18- to 21-year-old population as opposed to the under 18-year-old population. Those young people [18- to 21-year-olds] have a lot to say and are able to consent for themselves. There are very few emancipated youths in the foster care system. But there is extended foster care and a substantial number of youth between 18 and 21 who still participate in the system. Their locations and contact information are known to the [local department].

VDSS IRB Website Guidance for Researchers Studying Foster Care Children Population

Gail posed a question to Jamie and Carolyn about where the guidance is unclear or could be clearer that we could put on our VDSS IRB website that would be helpful for researchers. Carolyn had not seen any guidance on our webpage. She added that the hard part is what we are talking about is including individuals without parental consent. It may appear that research on these most vulnerable individuals is kind of exploitative; however, if we do not do this research, it lacks generalizability to this population. So it is a very delicate and we have to be cautious about how we deal with this.

Jamie added that in terms of guidelines it might just be that it is very plainly stated. If parental rights are not terminated, then you have to go to the biological family. If parental rights are terminated, then she does not know what the process is. [The VDSS IRB] needs to figure out what that process is and to make that very clear to those submitting IRB applications so that they can plan out their research and are accounting for making sure they are getting the appropriate levels of consent. In her proposal that was approved by VCU IRB, she stated that she would check with the case worker to see who was the appropriate person to sign consent. She did not specify that it would be an LDSS case worker or foster parent. She had put in her application that once youth provided permission for me to ask their case manager, she would ask [the case manager] who is the appropriate person for signed consent so she made sure that if it was a biological parent, then that is the person who would need to be contacted.

Gail mentioned that for those children who do not have a parent or guardian, there is no process in place and there is a reluctance from local agencies to appoint anyone or have the case managers step into that role. She also felt the state agency would not fulfill that role. Jamie, Carolyn, and Em agreed.

Gail added that we also do not have any advocate on our IRB who is equipped to do that either, and we do not have a mechanism in place to seek someone out. Andrew mentioned that in his interpretation of the rules an advocate would be in addition to the person who has to consent, not in lieu of a consenting parent or guardian.

Christopher added he thought with [133] different cities/counties/localities, you would likely get [133] different answers. That has been his experience with CSA contracts as a provider – every locality has its own language, again as another layer, about research and fundraising. He has to get photo releases when they put a child in an internal newsletter and an additional one if they want to post to social media of a piece of art, identified or unidentified. Depending on each locality, he has to go back to each contract to see what each one says with something as benign as [getting a photo release for] a piece of art. When talking about research, that is a different ball game.

Gail asked Jamie whether this discussion would make her consider changing her proposal. Jamie replied no. She had safeguarded her proposal knowing that she would be having a conversation, having spoken to Gail and VCU and knowing that we were not all on the same page. She had included that she would not decide who signs and would ask the case manager to identify who the appropriate person would be to provide consent. She is not going to change her proposal because she had accounted for all these things not knowing which way she needed to go. It is helpful for thinking down the line for future planning to be able to provide guidelines for her students or other colleagues who are interested in doing research with youth in foster care in Virginia.

Gail provided two examples from sources which stated their interpretation of the federal regulations: University of Virginia and University of Pittsburgh. She asked the group if they thought the language was clear on either website, and if any text should be borrowed to be posted onto our own IRB website. Comments could be provided to her after the meeting as well. Andrew and Gail would start drafting a guidance document with this compiled information to put on the webpage. They would need help from Em and other subject matter experts in this area to review and approve the drafted material. She asked for volunteers to work on the document or the content for our webpage. Jamie volunteered.

Waiver of Parent Consent Consideration While Drafting Guidance Document

The draft would go before the whole board and would be voted on so all would have a chance to give feedback. Gail asked for any parting thoughts. Jamie mentioned something to think about while writing this is that some states allow you to ask for a waiver of parental consent for wards of the state. But that she does not think that [applies to this case]. It would be really important for making clear to people who come from different states where, when working with older adolescents at transition age, and minimal risk, you may ask the IRB for a waiver of parental consent. She knows that is not the case here so making it very clear on the website. Gail added that she thought that relates to studying children who have previously been victimized – which would put them in an awkward position of obtaining consent from the parent if they were the perpetrator of that abuse. Jamie agreed that that is the language in some states. Gail thought that that was the case for Virginia as well, then deferred to Em. Em did not know with certainty

and did not think that this was particular to foster care children. If there was a carve out for that, she was not familiar with it.

Action Items

Gail, Andrew, Em and Jamie will work together to draft a guidance document regarding participation of foster care children in research and the issue of parent, guardian, or legally authorized representative consent. The final draft document will be reviewed by the rest of the IRB before posting on the website.

ADJOURNED TIME:

The meeting adjourned at 1:53 pm.

MOTION:

N/A

DECISION AND VOTING

| DECISION AND VOTING: | | | | |
|-------------------------------|---------------------------------------|--|-----------------------------------|----------------|
| | Scientist (S) Non-scientist (N) | | In person (I) Teleconference (TC) | |
| Present | | IRB Member | | Telephone (TP) |
| | S | Gail Jennings, PhD |) (Chairperson) | TC |
| | S | Jamie Cage, PhD | (VCU) | тс |
| \boxtimes | N | Christopher Campl | bell, MBA, MPA | тс |
| | N | Disse, Mary, B.A. (| (VDSS) | тс |
| \boxtimes | S | Hawley, Carolyn, F | PhD, CRC (VCU) | TC |
| \boxtimes | S | Nair, Dev, PhD (Di | BHDS) | TC |
| \square | S | | MSW, LCSW (VDSS) | TC |
| \boxtimes | N | Tim Reddish, MSV Catholic Charities) | тс | |
| | S | Jeff Price, PhD (VDSS; Ombudsman; Alternate) | | тс |
| \boxtimes | S | Temoney-Porter, Tamara, PhD (Hampton DSS) | | TC |
| \boxtimes | N | Stephen Wade, MUP (VDSS) | | TC |
| | S | Andrew Sell, MBA (VDSS, Co-Coordinator) | | тс |
| Additional Participants: Name | | Role during the meeting: | | |
| | | | | |
| | | | | |

Appendix E: Studies Approved by Full Board Review Procedures, SFY 2023

| Project ID | IRB_2023-03 | Submission Date | 9/12/2022 |
|------------------------|--|--------------------------|-----------|
| Project Title | Using Play to Cultivate Resilience Within Foster Families: An Occupational Therapy-Based Community Program | | |
| Submission Type | Initial Review | Review Type | Full |
| Agency Sponsor | None | | |
| Funding | None | | |
| Investigator(s) | Andrea Poe (doctoral student) | | |
| PI Affiliation | Shenandoah University School Health Professions | | |
| Approved | 11/7/2022 | Approval End Date | N/A |
| Modification(s) | 1/7/2023 | | |
| Status | Closed (5/14/2023) | | |

Description: This study invited foster parents to voluntarily participate in an 8-week, 16-session training program. The course had a mix of in-person and virtual classes and pre-recorded presentations. The training, which involved role play exercises, games, crafts, self-reflection, and group discussions, focused on educating parents about trauma-informed care, emotional regulation, and overcoming barriers. The purpose of the study is to determine the efficacy of occupational therapy-based play intervention for building resilience factors in foster parents so they may model resilient behaviors to foster children. The objective was to improve foster parents' perceived connection with other family members, including foster children, through improved self-regulation, responsive parenting, and establishing defined roles, routines.

As the study site mentor, the Family Services Supervisor (FSS) for Frederick County invited eligible families from the county and surrounding areas to participate. The target was to recruit eight families (up to 16 parents), but only seven adults enrolled in the study and five completed the training. Participants must be 21 or older, have internet access, and live in the catchment area to participate. Families receiving family counseling services, serving as a therapeutic home, or caring for a foster child receiving VEMAT services were ineligible. To enroll, the parents completed an online Parent Information form. A study ID was assigned to each participant.

Parents completed pre- and post-training surveys online. The surveys were adapted from the Parenting Stress Index (4th ed. Short Form). Parents who attended at least one class per week and completed the surveys earned a chance to win a \$100 gift certificate (one per family). Participants had the option to drop out of the study at any point. Participants may remain in the study even if the foster care placement disrupts. Sessions were recorded.

In the original submission, the investigator proposed asking foster youth ages seven and older to complete a brief survey about the dynamics occurring in the foster home, but not attend the training. The FSS would provide consent for the children, and older youth would provide assent. However, state laws do not permit the LDSS staff to consent for foster youth. Per IRB recommendations, inclusion of children in the study was not approved. In addition, none of the study forms could collect the names of any children living in the foster home. Following changes to the protocol, the board unanimously approved the study on 11/7/2022.

Modifications: All classes were virtual, thus eliminating the option to attend in-person.

Appendix F: Studies Approved by Expedited Review Procedures, SFY 2023

| Project ID | IRB_2023-01 | Submission Date | 6/29/2022 |
|------------------------|--|------------------------|-----------|
| Project Title | Virginia Department of Social Services Post Adoption Evaluation | | |
| | | | |
| Submission Type | Initial Review | Review Type | Expedited |
| Agency Sponsor | VDSS Family Services | | |
| Funding | None | | |
| Investigator(s) | Berenice Rushovich, MSW | | |
| PI Affiliation | Child Trends | | |
| Approved | 8/17/2022 | Approval End Date | N/A |
| Modification(s) | 10/7/2022; 10/27/2022; 12/13/2022; 1/24/2023; 2/7/2023; and 3/9/2023 | | |
| Status | Ongoing | | |

Description: From 2018 to 2020, Child Trends conducted a needs assessment for the purpose of redesigning contracts for delivery of post-adoption services and supports to adoptive families in Virginia. The purpose of this study is to assess which services and supports families continue to need to prevent adoption instability (disruptions and dissolutions). The study will conduct surveys and semi-structured focus group interviews with adoptive parents, adults formerly in foster care who were adopted, and adoption staff in local department of social services (LDSS) and private agencies. Child Trends will analyze administrative data on disturbed adoptions. The project has the following goals: 1) Assess whether or not the newly redesigned post-adoption supports and services are affecting the rate of adoption stability and reducing the number of adopted children requiring prevention/intervention services or returning to the foster care system; 2) Understand the type of post-adoption services (incl. prevention/intervention services) and supports families need to prevent disturbed adoptions; and 3) Understand the level of adoption competence of adoption providers and how that may play a role in the effectiveness of post-adoption services. Child Trends will use the findings to improve post-adoption services and supports and design better technical assistance for VDSS, LDSS, and private agencies.

Through referrals and advertisements, the LDSS and private agencies will recruit adoptive families and former foster youth to participate in the study. Participants (adoptive parents and young adults) will be paid \$50 for interviews and \$25 for completing online surveys. The semi-structured interviews will take 60 minutes to complete. Child Trends will receive de-identified client-level data for secondary data analysis. Only case and client IDs will be included.

Modifications: 1) waiver of documented informed consent for parent focus groups; 2) the PI will email the Adoptive Parent Survey directly to participants upon request to prevent bots/scammers from completing the survey; 3) staff interviews will now include a consent process similar to the one used for adoptive parents; 4) recruitment flyers for youth participants will clarify the age inclusion criteria and make it more noticeable; 5) the study will allow participants to contact the research staff via text in addition to email; 6) further changes to the recruitment materials targeted to local agency staff and adoptive parents; 7) addition of a 30-minute survey to be sent to LDSS staff and consortium providers. The survey will assess adoption workers' competencies, experiences, and attitudes, as well as need for support and training in delivering adoption services to adoptive and guardianship families. The consent language is included at the start of the survey. The survey will ask for background information but no personally identifiable information.

| Project ID | IRB_2023-02 | Submission Date | 8/31/2022 |
|------------------------|---|--------------------------|-----------|
| Project Title | Immigrant Access and Participation in DSS-Sponsored Education and Training Programs | | |
| Submission Type | Initial Review | Review Type | Expedited |
| Agency Sponsor | None | | |
| Funding | None | | |
| Investigator(s) | Sarah Smith, PhD, MPA | | |
| PI Affiliation | VDSS Research and Planning | | |
| Approved | 9/20/2022 | Approval End Date | N/A |
| Modification(s) | None | | |
| Status | Ongoing | | |

Description: This study involves secondary data analysis to understand the barriers that work-authorized immigrants may face in accessing TANF workforce development programs. The study will address two research questions related to disparate access: 1) Is there equity in TANF participation overall on the basis of qualified immigrant status? 2) Is there equity in access across TANF workforce programs for eligible immigrants, as compared to U.S.-born citizens in Virginia?

Data for the analysis will be obtained from the VaCMS, the Benefit Program case management system. The analysis will compare participation in VIEW, TANF-UP, and VTP programs on the basis of immigration status, using descriptive statistics, statistical tests, and OLS regressions. Waiver of informed consent was approved.

The case ID will be used to link data tables and then removed from the analysis dataset (the actual IDs will be maintained in a separate encrypted file). The PI plans to analyze overall participation in VIEW, participation in individual program components (i.e., job readiness, job training, subsidized employment), spell length, and receipt of work supports. This analysis will be contextualized using statistics from the U.S. Census Bureau's American Community Survey and other publicly available data. The study will compare outcomes for U.S.-born citizens, naturalized citizens, and non-citizens. The results of this analysis will be presented in a report to ONA staff. A protocol is in place to safeguard private, personally identifiable information.

| Project ID | IRB_2023-04 | Submission Date | 9/30/2022 |
|------------------------|---|------------------------|-----------|
| Project Title | Energy Assistance Program (EAP) Cooling and Heating Surveys | | |
| | | | |
| Submission Type | Initial Review | Review Type | Expedited |
| Agency Sponsor | None | | |
| Funding | None | | |
| Investigator(s) | Sandra Lamm, PhD; Sarah Smith, PhD, MPA | | |
| PI Affiliation | VDSS Energy Assistance Program | | |
| Approved | 10/6/2022 Approval End Date N/A | | |
| Modification(s) | 11/30/2022; 4/20/2023 | | |
| Status | Ongoing (Cooling Assistance Survey completed) | | |

Description: The VDSS Energy Assistance Program will administer an online survey to random samples of households that received home energy assistance during the FY 2022 cooling and heating seasons. The head of household (case lead) will be asked to participate. Separate surveys will be sent at the close of each season. The cooling assistance survey will be sent in October 2022 to 4,771 clients, and the heating assistance survey will be sent in Spring 2023 to 6,454 clients. Using client data from the program, survey invitations will be sent by email or postal mail, depending on the client's preferred method of contact. VDSS will send a pre-notification letter to explain the purpose of the surveys and the terms of participation.

Subjects will opt-in to the survey (answering "I agree" to the first question) before continuing with the rest of the survey. Study participants will be asked a series of questions about how their cooling or heating bills affected their lives, reasons for needing home energy assistance, other organizations from whom they received cooling or heating assistance, how much of their cooling or heating costs were covered by assistance, how they heard about EAP, and what actions they have taken to reduce their energy usage. Findings from the surveys will be included in a report to the Virginia General Assembly. The estimated time to complete the surveys is five minutes each. Participation is completely voluntary; there is no reimbursement or incentive for participation. The survey will be available in Spanish.

To reduce the number of questions in the survey, subjects will be asked to provide their case ID to enable the researchers to link survey responses to demographic and case information from the EAP data system. Respondents can opt-out of providing their case ID by skipping the question.

The survey and administrative data files will be stored on secure devices and VDSS servers. After linking the survey and administrative data, case IDs will be replaced or removed. No personally identifiable information (e.g., name, SSN) will be saved in the data file.

Modifications: 1) Minor changes to the wording of some of the Cooling Survey questions and update to the time for the deployment of the survey; 2) due to a low response rate with the Cooling Survey, VDSS will contact clients by mailed letter (award notice of services received) that includes information about the Heating and Crisis Survey. In addition, clients who have an email address on file will be notified about the survey.

| Project ID | IRB_2023-05 | Submission Date | 10/14/2022 | | |
|------------------------|---|---|------------|--|--|
| Project Title | Increasing the tax credit take-up through understanding barriers in tax filing among the VDSS clients | | | | |
| Submission Type | Initial Review | Initial Review Review Type Expedited | | | |
| Agency Sponsor | None | | | | |
| Funding | None | | | | |
| Investigator(s) | Jiwoo Pierson, PhD and Jeff Price, PhD | | | | |
| PI Affiliation | VDSS Research and Planning | | | | |
| Approved | 11/3/2022 | Approval End Date | N/A | | |
| Modification(s) | 1/30/2023 | | | | |
| Status | Ongoing | | | | |

Description: As required by COV 63.2-527, VDSS notifies clients about tax credit availability each year to increase uptake of the Earned Income Tax Credit (EITC) and the Child Tax Credit (CTC) among income-eligible individuals. While providing information about the tax credits is a significant step towards helping moderate to low-income families, researchers do not understand why few Virginians use available credits that can offset income tax and encourage work participation. VDSS will send a brief online survey to a sample of DSS clients with reported earnings who did not file a state tax return in 2021 ("non-filers"). The survey will ask if the respondent filed taxes, their reasons for not filing, and their preferred method of learning about tax credit benefits and free income tax preparation services. The PI will create a sample using Benefit Program client data (from VaCMS), quarterly UI earnings data from the Virginia Employment Commission, and 2021 tax records from the Virginia Department of Taxation. Since this is a pilot project, the survey will have an open-ended question to ask about the survey process. The survey is in English only as the majority of non-filers indicated their primary language was English.

Clients will receive the survey by email, SMS/text, or postal mail, based on preferred method of contact. Email and text notifications will be sent via Qualtrics; non-responses can be tracked and reminder notifications sent to non-responders. To reduce the length of the survey, the researcher will use the individual's client ID to link survey responses with administrative data and perform subgroup analyses. The remainder of clients who prefer mail will receive a letter with the survey link printed. The latter group will be asked to enter their client ID on the survey.

The survey results will be used to improve the agency's efforts to increase tax credit uptake and provide appropriate support to clients. Participation in this survey is voluntary. Informed consent to complete the survey will be collected on the first page of the survey. The responses will be linked to the client data and tax and income records. Survey responses and client information will be stored on a VDSS-owned secure cloud-based sites (OneDrive and Sharepoint). VDSS will take measures to store sensitive information in a secure manner.

Modifications: Due to a low response rate, the investigator is sending the survey to a larger sample of DSS clients as well as individuals (non-clients) who solicit information about DSS. The survey link will be inserted in routine business correspondence. The survey link is posted on the DSS public web site. The survey responses will not be linked to any client data; demographic information will be collected on the survey. The survey invitation will be sent to individuals who have not yet filed a tax return in 2022 or are having difficulty filing.

| Project ID | IRB_2023-06 | Submission Date | 11/15/2022 | | | |
|------------------------|--|--------------------------------------|------------|--|--|--|
| Project Title | The Schooling Experiences of Virginia Teens in Foster Care Study | | | | | |
| | | | | | | |
| Submission Type | Initial Review | Initial Review Review Type Expedited | | | | |
| Agency Sponsor | None | | | | | |
| Funding | Virginia Department of Education | | | | | |
| Investigator(s) | Jamie Cage, PhD; Nicole Corley | | | | | |
| PI Affiliation | Virginia Commonwealth University, School of Social Work | | | | | |
| Approved | 1/12/2023 | Approval End Date | N/A | | | |
| Modification(s) | 6/29/2023 | | | | | |
| Status | Ongoing | | | | | |

Description: Through a series of personal interviews and focus group meetings, youth in foster care or other out-of-home (kinship) placements will be asked about their personal experience with school stability and school engagement. This study aims to understand how foster care impacts teens' school experiences. Youth will be invited to share their experiences at a Virginia Department of Education (VDOE) stakeholder meeting and advise the group on how to improve school stability and engagement for other youth in foster care. The study intends to recruit a sample of 30 youth (5-6 per region). As recommended by the IRB, the study will recruit only youth who are 18 and older. To qualify for the study, youth must 1) currently be in foster care or recently have left care in the last six months, 2) currently attend public school (or left in the last six months); 3) been in foster care for a minimum of six months; and 4) experienced at least one foster care placement. Youth who reside in a residential facility (e.g., group home), attend a residential or private day school program, or are home-schooled will be excluded.

Using convenience and snowball sampling, the study team will recruit participants through social media, word-of-mouth, flyers, referrals, etc. from local social services agencies. If interested, youth can contact the study team through an online form. The study team will screen out ineligible individuals before any contact. The staff will meet with eligible subjects to review the consent form and go through a 48-hour waiting period before obtaining signed consent and scheduling the first interview or focus group. Because participants are 18 and older when they enroll, they are not required to obtain parental consent, even if they remain in transitional foster care as adults.

Subjects will participate in two interviews and two focus group meetings (90 minutes each). Youth have the option to meet virtually and use pseudonyms during the meetings. Meetings and interviews will be recorded and transcribed. The first sessions will explore youth experiences with school stability and their past educational experiences. The latter sessions will be about school engagement. Youth will not be asked about their experience in in the foster care/child welfare system. Youth will be invited to a planning session before attending the VDOE stakeholder meeting, where study results will be presented. Participants are encouraged, but not required to attend all events during the 12-month period, and they will be compensated with a \$30 gift card per event (up to \$180 total). The study poses minimal risk. Participants will be asked to respect the privacy of others during focus groups. The subject's name will not be linked to information they disclose at any meetings. Subjects are informed that if they disclose any information that suggests potential harm to self or others, the research team will report this information.

Modifications: Waiver of documentation of informed consent is approved.

| Project ID | IRB_2023-08 | Submission Date | 2/8/2023 |
|------------------------|--|-------------------------|-----------|
| Project Title | Vicarious Trauma in the DSS Human Services Workforce | | |
| | | | |
| Submission Type | Initial Review | Review Type | Expedited |
| Agency Sponsor | None | | |
| Funding | None | | |
| Investigator(s) | Laurie Crawford, MPA; Stacie Vecchietti, MSW | | |
| PI Affiliation | VDSS Office of Trauma | a and Resilience Policy | |
| Approved | 3/13/2023 Approval End Date N/A | | |
| Modification(s) | 4/26/2023; 5/3/2023 | | |
| Status | Ongoing | | |

Description: Sponsored by the Office of Trauma and Resilience Policy (OTRP), the purpose of this pilot project is to get feedback from Benefit and Family Services front line workers and supervisors in local departments and Regional Practice Consultants in the regional offices to learn more about the prevalence of vicarious trauma and about employees' coping strategies and agency efforts to mitigate trauma in the workforce. The study will also focus on how the COVID-19 pandemic played a role. Vicarious traumatization is a negative reaction to trauma exposure and includes a range of psychosocial symptoms. Results from this pilot, qualitative study will, in turn, guide the design of future quantitative studies and inform DSS policy and practice around workforce supports to mitigate the effects of vicarious trauma.

Information will be collected through several (22) online focus group interviews with groups segregated by role type (frontline staff, supervisors, and regional consultants) and program area (Family Services vs. Benefit Programs). frontline staff vs. supervisors vs. regional practice consultants) between. Ten participants will be recruited for each group, for a total of 220 subjects. Each focus group will last no longer than 75 minutes. There is no monetary incentive to participate.

Subjects will be recruited via email sent to local agencies and regional offices. Employees who are interested in participating will complete an online interest form. Scheduled participants will receive the informed consent form in advance of the focus group meeting. At the start of the focus group, the facilitator will review the consent language, answer questions, and obtain verbal consent from each participant. Participants will be reminded to not disclose any information shared by others. If a participant indicates that they may harm themselves or others, it will be reported to the local mental health crisis team.

Each session will be audio and visually recorded; participants have the option to turn their web camera off, not respond to a specific question, and leave the focus group at any time. No PII will be collected during the focus group. However, participant names recorded in the transcript will be replaced with a study ID. The recordings will be destroyed after the transcriptions have PII redacted. The study poses minimal risk to subjects.

Modifications: 1) To improve the flow of conversation, the order of discussion questions was rearranged; 2) due to difficulty recruiting a sufficient number of participants within each region, some regions are combined. The discussion groups will remain segregate by role type.

| Project ID | IRB_2023-15 | Submission Date | 4/25/2023 |
|------------------------|---|--------------------------|-----------|
| Project Title | Kinship Foster Placement: Analysis of Current Trends | | |
| | | | |
| Submission Type | Initial Review | Review Type | Expedited |
| Agency Sponsor | None | | |
| Funding | None | | |
| Investigator(s) | Sarah Smith, PhD, MPA; Sandra Lamm, PhD; Andrew Sell, MBA | | |
| PI Affiliation | VDSS Office of Research | ch and Planning | |
| Approved | 5/12/2023 | Approval End Date | N/A |
| Modification(s) | None | | |
| Status | Ongoing | | |

Description: The research project will involve secondary data analysis of administrative data from the child welfare information system (OASIS) to describe children and guardians in kinship versus non-kinship placements in Virginia's child welfare system. This research will also examine local trends and use publicly available data about the local social services agency and the community they serve. The research questions are: 1) How do kinship foster placements differ from non-kin foster placements?; 2) Given that Virginia uses a "state supervised, locally administered" governance model, is there a relationship between local agency context and kinship placement rates?; and 3) Are there differences in child outcomes by placement type? Conclusions drawn from this research will inform future research projects.

The investigators will perform descriptive and comparative analyses by using administrative client data from OASIS for cases active between CY 2018 and 2022. The file will contain data records on 25,000 children in foster care and 15,000 adult caregivers. The investigators will examine differences in child and guardian demographic characteristics (e.g., age, sex, race, disability status, marital status, income/poverty status) and case characteristics (e.g., removal reasons). This project will also consider differences in foster care outcomes. The investigators will also use Census data (e.g., urban/rural designation) and information about the local social services agency (e.g., agency level, region) to analyze if environmental or contextual factors correlate with kinship placements and outcomes.

The project will start in May 2023 and take about two years to complete (through May 2025). A waiver of informed consent has been submitted. Case and client ID in the administrative data files will be used for linking longitudinal yearly datasets to construct the final analysis dataset. The following PII data elements will be removed from the data set used for analysis: name, Social Security Number, home address, and phone number. All preliminary work requiring identifying information for matching across data sets will be conducted prior to analysis. Remaining case information will be maintained on VDSS-issued devices and networks. Access will be restricted to ORP research staff. All PII will be maintained on password-protected laptops and/or the role-protected network storage systems; all systems are maintained by VDSS. Data transmission over the internet will be encrypted per VDSS maintained protocols and software. The risk to participants, which is limited to data breaches, is minimal.

| Project ID | IRB_2023-16 | Submission Date | 4/7/2023 | | |
|------------------------|---|--------------------------------------|----------|--|--|
| Project Title | Expanding Education and Training Opportunities for Work-Eligible Public Assistance Recipients | | | | |
| Submission Type | Initial Review | Initial Review Review Type Expedited | | | |
| Agency Sponsor | None | | | | |
| Funding | None | | | | |
| Investigator(s) | Jiwoo Pierson, PhD; Jeff Price, PhD | | | | |
| PI Affiliation | VDSS Office of Research | ch and Planning | | | |
| Approved | 5/1/2023 Approval End Date N/A | | | | |
| Modification(s) | None | | | | |
| Status | Ongoing | | | | |

Description: VDSS partners with educational organizations such as the Virginia Community College System (VCCS), Merit America, Year Up, and Per Scholas, to connect VDSS clients to tuition-free training programs in high-demand job sectors. Prior evidence demonstrates similar programs improve multiple economic outcomes of participants, including higher earnings and more consistent employment. The outreach is a part of an ongoing effort to increase VDSS clients' education and credentials, which will ultimately lead to employment with well-paying wages to support families. The outreach will be targeted to TANF-VIEW and SNAP E&T clients who generally fall within the work-eligible population. These training programs will meet the work requirement of VDSS benefits program, if necessary.

Using contact information (email address and/or mobile phone number) from the Benefit Programs case management system (VaCMS), outreach messages along with a link to a short online survey will be sent by email or text (SMS) message via Qualtrics to clients who qualify for this study. Participation is voluntary. Consent language appears as a preamble to the survey. This survey is intended to collect information on barriers clients face in keeping their current job(s) and/or difficulties they expect to face when enrolling in the advertised training programs. Results from this survey will allow the programs to better understand why some clients may opt to not participate in education and training activities, as well as how to better support them to reach future financial stability.

Survey responses will be linked to VDSS administrative records to allow the investigators to analyze demographic and case factors that correlate with barriers to employment and training. PII (e.g., client ID, full name, contact information) which is extracted from VaCMS will be removed from the final analysis dataset. With the client's permission, the study team will share information about the individual's interest in participating in employment training and reported obstacles to participation in training with the client's case manager. Otherwise, the client's survey responses will remain confidential.

| Project ID | IRB_2023-17 | Submission Date | 5/1/2023 |
|------------------------|---|--------------------------|-----------|
| Project Title | TANF Client Surveys (Application and Customer Satisfaction) | | |
| | | | |
| Submission Type | Initial Review | Review Type | Expedited |
| Agency Sponsor | None | | |
| Funding | None | | |
| Investigator(s) | Heeju Jang-Paulsen, PhD; Sandra Lamm, PhD | | |
| PI Affiliation | VDSS Office of Research | ch and Planning | |
| Approved | 5/23/2023 | Approval End Date | N/A |
| Modification(s) | None | | |
| Status | Ongoing | | |

Description: This is a pilot project for the TANF Application Survey and TANF Customer Satisfaction Survey that will be implemented on an ongoing basis in 2024. A report will be shared with TANF program administrators and may be disseminated more broadly to the research community. The Application Survey will examine TANF recipients' experiences with the application process. It will ask about reasons for applying for TANF, difficulty completing the online application, their understanding of program rules, and their experience at the intake interview. Respondents will be recruited among the TANF cases whose benefits were approved in May 2023, a month prior to when the survey sample is extracted from VaCMS. The survey will be deployed June 12-July 14. This is to ensure that the experience of applying for TANF is recent enough to be easily recalled.

The Customer Satisfaction Survey will focus on clients' experiences with the services and assistance they received. Two versions of this survey are available for those who only received TANF benefits and those who also participated in the VIEW program. In addition to the circumstances that led them to apply for TANF and their understanding of program rules, the survey will inquire about which types of services or assistance they received, how helpful the services or assistance were, and their experience with their case workers. For this survey, we will sample among the TANF cases whose benefits were approved 6 to 8 months prior to the survey (October through December 2022). By the time they take the survey (June 12 through July 14), they should have sufficient experience with the programs.

Using Qualtrics, a notification with the link to the applicable survey will be sent via email or SMS text messaging, depending on the client's preferred method of communication as recorded in VaCMS. If neither is employed, they will be notified by letter (mail). In both surveys, respondents will be asked to provide their TANF case number so that their survey responses may be linked with administrative data to enable additional analyses. The client's participation, including providing the case number, is voluntary. Informed consent will be collected upfront at the beginning of the survey. Participants have the option to skip entering the case ID later in the survey. Clients whose primary language is Spanish will receive translated notifications and surveys.

| Project ID | IRB_2023-18 | Submission Date | 6/2/2023 |
|----------------------|---------------------------------------|------------------------|-----------|
| Project Title | Evaluation of the CSE TANF Supplement | | |
| | | | |
| Submission Type | Initial Review | Review Type | Expedited |
| Agency Sponsor | None | | |
| Funding | None | | |
| Investigator(s) | Sarah Smith, PhD, MPA | | |
| PI Affiliation | VDSS Office of Research | ch and Planning | |
| Approved | 6/22/2023 Approval End Date N/A | | |
| Modification(s) | None | | |
| Status | Ongoing | | |

Description: The study will evaluate a 2016 policy change regarding the distribution of child support payments for TANF clients. To be eligible for TANF, state law stipulates that custodial parents must cooperate with the Division of Child Support Enforcement, when applicable. Prior to the reform, any collection amount above \$100 was absorbed by the government to reimburse the costs of public assistance. The 2016 General Assembly directed DSS to pass through up to an additional \$100 of paid child support as a TANF supplement for two-child families (one-child families still receive only \$100 in pass-through). This study will assess the effect of this change on obligors' behavior and TANF program outcomes by comparing one- and two-child families.

Using administrative data from the TANF and the Child Support Enforcement programs, this project will address these two sets of research questions: (1) Does the new pass-through policy increase the likelihood the non-custodial parent makes any child support payment, both during and after the TANF spell? Does this pass-through policy increase the share of the obligation paid, both during and after the TANF spell? (2) Does the supplemental payment affect the amount of time he family receives benefits (spell length)? Child Support Enforcement staff will provide the child support enforcement data from APECS; the PI has access to TANF data in the DSS Data Warehouse. Other publicly available data from the U.S. Census Bureau and other government public use datasets may also be incorporated to provide context regarding the findings from this secondary research.

The data will be stored on VDSS-issued devices and networks. Only the PI and possibly other ORP staff will have access to the data. A waiver of informed consent was approved. Data for at least 36,000 parents (custodial and non-custodial) and 20,000 children will be used in this study. The study is expected to end in June 2026.

This study findings will be shared with VDSS staff and leadership and may be shared with policymakers and other stakeholders. Findings may be disseminated to the broader research community.

| Project ID | IRB_2023-19 | Submission Date | 6/6/2023 |
|------------------------|--|------------------------|-----------|
| Project Title | Engagement with Older Youth and Out-of State Families for the Interstate Compact on the Placement of Children (ICPC) Permanency Planning | | |
| Submission Type | Initial Review | Review Type | Expedited |
| Agency Sponsor | None | | |
| Funding | None | | |
| Investigator(s) | Chanda Yarbrough, MEd | | |
| PI Affiliation | VDSS Division of Family Services | | |
| Approved | 7/6/2023 | Approval End Date | N/A |
| Modification(s) | None | | |
| Status | Ongoing | | |

Description: The purpose of this study is to explore the strategies used by VDSS to engage older youth (14 years and older) and their families, who are seeking guardianship or adoption through the Interstate Compact for the Placement of Children (ICPC) process. This study will provide information about what strategies are needed to effectively engage youth and families during the planning, placement, and permanency phases of an ICPC case. The investigator will conduct personal interviews with 20 staff members and 20 adoptive parents and a virtual focus group with 10 adults who were adopted out-of-state. Family and youth interviews will ask how LDSS engaged with them during the phases of the ICPC process. Staff interviews will assess the extent to which they engaged youth and their families during all phases of the ICPC process.

Adoptive parents and youth will be recruited through local, state, and federal partners and member networks for adoptive families. Although the goal is to recruit participants who were recently involved in an ICPC case, there is no prescribed time frame for when the ICPC case was active. Consent will be obtained prior to participating in the interviews/focus groups. Interviews may be conducted by phone or virtually through Teams. Focus group interviews with former foster youth will be virtual; participants have the option to turn off their camera. Interviews and focus group meetings will be recorded and transcribed. Study IDs and aliases will be used in place of names, and personally identifiable information will be redacted from transcriptions. The study is expected to start June 2023 and be completed by the end of 2023. Parents and former foster youth will be entered in a raffle drawing to receive a \$25 gift card as compensation.

In addition, the investigator will conduct a case review of 40 ICPC cases that closed in 2020-2022. The case documents, containing narrative information about the child's case, will be obtained from the National Electronic Interstate Compact Enterprise (NIECE). The review will assess LDSS engagement practices within the ICPC referral. Cases will be sampled from each VDSS region for select age groups. Case information and files from OASIS will also be used to assess local agency engagement practices. PII will not be redacted in the case review files received by the PI. However, no PII (e.g., child's name) will be recorded on the case review checklist or entered/stored in the final data analysis file. None of the information disclosed during the interviews and focus group will be linked to case review data.

Although participants may feel uncomfortable with certain topics discussed at the meetings, the study poses minimal risk to subjects. Findings will be presented to the Minority Professional Development Leadership program of AdoptUsKids and the Virginia Department of Social Services.

Appendix G: Studies Determined Exempt from Federal Regulations, SFY 2023

| Project ID | IRB_2023-07 | Submission Date | 12/7/2022 |
|------------------------|---|--------------------------|-----------|
| Project Title | Building a Stronger Child Care System in Virginia: Evaluating the | | |
| | subsidy system in Virginia using | secondary administrativ | ve data |
| Submission Type | Initial Review | Review Type | Exempt |
| Agency Sponsor | Virginia Department of Education | | |
| Funding | ARPA-Child Care & Dev. Block Grant subrecipient award to UVA | | |
| Investigator(s) | Daphna Bassok, PhD; Katherine Miller-Bains, PhD | | |
| PI Affiliation | University of Virginia | | |
| Approved | 12/22/2022 (Categories 2 & 5) | Approval End Date | N/A |
| Modification(s) | None | | |
| Status | Ongoing | | |

Description: The Virginia Department of Education (VDOE), University of Virginia, and VDSS have a mutual interest and need to evaluate the impact of changes in child care funding and policy on families, children, and child care provider sites in Virginia. In this study, UVA will analyze administrative data from VDOE and VDSS to evaluate the impact of recent policy reforms, which include lowered copayments for families, expanded eligibility for families, and increased reimbursement rates for approved subsidy vendors, on participation in Virginia's Child Care Subsidy Program (CCSP).

The secondary data on child care sites comes from VDOE's child care licensing program and includes information about child care sites, such as location, provider type, license type, rate charged for care, capacity, and participation in the child care subsidy program. The secondary data about CCSP clients comes from VDSS and includes information about children and families' use of subsidies, including dates of initial application/recertification, dates/amounts of payments conferred to sites for care, characteristics of clients and their families, and reported reasons they exit the program. Both datasets will contain data collected from 2017 to 2024. Both data sets will be linked through common identifiers and then replaced with alphanumeric IDs assigned by the state. No PII will be shared. Together, the data will allow the agencies to explore utilization of the subsidy program over time and the influence of policy changes on families' and sites' participation in CCSP.

The UVA research team will perform descriptive analyses to examine whether (a) the number of subsidy-accepting child care sites increased after changes to the reimbursements rates paid to providers enrolling children through the CCSP, (b) the number of children participating in the CCSP increased at sites already accepting subsidies prior to the policy change and corresponding increases in revenue from the CCSP for these sites, (c) the duration of care for children participating in CCSP increased after expanding program eligibility and lowering copayments, and (d) the characteristics of families (e.g., income, race, locale) and sites (e.g., site type, region, locale) participating in the CCSP changed after the new policies were instituted.

| Project ID | IRB_2023-09 | Submission Date | 2/13/2023 |
|-----------------|---------------------------------|--------------------------|-----------|
| Project Title | 2023 Resource Parent Survey | | |
| | | | |
| Submission Type | Initial Review | Review Type | Exempt |
| Agency Sponsor | N/A | | |
| Funding | None | | |
| Investigator(s) | Garrett Jones, LCSW; Julia Ruba | rth | |
| PI Affiliation | VDSS Division of Family Service | es | |
| Approved | 2/13/2023 (Category 2) | Approval End Date | N/A |
| Modification(s) | None | | |
| Status | Ongoing | | |

Description: The Division of Family Services is conducting a survey of resource families who are approved by either the local departments of social services or local child placing agencies to serve as foster, kinship or adoptive placements for children in foster care. Using a snowball sampling technique, DFS will ask local DSS agencies, Division of Licensing staff, and LCPAs to inform resource families as part of its subject recruitment. The online survey will collect some demographic information, but otherwise will not collect PII (no administrative data will be linked to survey responses). The survey has questions pertaining to the following topics: number of child placements and disruptions, receipt of foster parent training, type of communication with LDSS staff, assessment of the local case worker, home visits, involvement in family partnership meetings, Child and Family Team Meetings, court hearings and case planning, need for and use of respite care, relationship with the biological parents, normalcy practices, availability of crisis resources, and post-adoption services. The purpose of the survey is to improve delivery of services to resource parents. The survey responses will be reviewed internally only by state staff.

| Project ID | IRB_2023-10 | Submission Date | 2/13/2023 | |
|------------------------|---|------------------------|-----------|--|
| Project Title | Experiences Working in Child Welfare Study | | | |
| | | | | |
| Submission Type | Initial Review Review Type Exempt | | | |
| Agency Sponsor | VDSS Division of Family Services | | | |
| Funding | None | | | |
| Investigator(s) | Rebecca Gomez, PhD, LCSW; Naomi Reddish, MSW | | | |
| PI Affiliation | Virginia Commonwealth University, School of Social Work | | | |
| Approved | 3/6/2023 (Category 2) Approval End Date N/A | | | |
| Modification(s) | None | | | |
| Status | Ongoing | | | |

Description: The purpose of this study is to evaluate the effectiveness of Virginia's Title IV-E Child Welfare Stipend Program (CWSP) on job preparedness for child welfare workers currently working in local or state agencies.

The first phase is an online survey targeted to alumni of the CWSP who may or may not be currently working in local or state local departments of social services. The study will compare social services workers who received CWSP training and those who did not. The survey will take 15-30 minutes to complete. No PII will be collected in the main survey. Survey respondents can enter a raffle for a chance to win a \$50 electronic gift card incentive. The raffle entry form is

separate from the main survey and responses will not be linked to participants' names and contact information entered in the raffle entry form. If interested in participating in a focus group, participants will be redirected to a separate form.

In the second phase, the study will conduct focus groups to gain a deeper understanding of the experiences of Virginia's CWSP alumni and local social services supervisors regarding the preparedness of students for child welfare work. Subjects will be drawn from a sample of previous survey respondents who agreed to further participation in the focus group. Participants must be 18 years or older and have either been a student participant in the CWSP, supervised a student in a local agency, or managed a child welfare agency while students were employed in the local agency. Participants will be assigned a study ID. The meetings are virtual and will be recorded. Sessions are 90 minutes each and will be transcribed (recordings will be deleted after transcription). Participants will be given a \$50 electronic gift card incentive. The findings of this study can inform ways to improve child welfare training, policy, and practice.

The study will recruit potential participants through flyers, posts on the VDSS intranet (FUSION), employee and alumni listservs, and professional organizations (e.g., VLSSE). The investigators will also try to recruit CWSP alumni through the CWSP University Coordinators and its Advisory Committee. Participants are given an information sheet before completing the survey and/or attending focus groups. Waiver of documentation of informed consent was approved. To recruit subjects, notices will be sent to approximately 6,000 family services workers (including supervisors) in local agencies and/or former alumni. Inclusion criteria for the survey: 1) age 18 or older; 2) currently work in a local department of social services doing some aspect of child welfare work and/or participated in the CWSP. The data collection will occur during three months in spring 2023.

| Project ID | IRB_2023-11 | Submission Date | 2/21/2023 | |
|-----------------|---|------------------------|-----------|--|
| Project Title | Fostering Responsible Parents in Virginia | | | |
| Submission Type | Initial Review | Review Type | Exempt | |
| Agency Sponsor | N/A | | - | |
| Funding | Admin. for Children & Families/ Office of Child Support Enforcement | | | |
| Investigator(s) | Mariellen Keely; Taylor Ashe | | | |
| PI Affiliation | VDSS, Division of Child Support Enforcement | | | |
| Approved | 3/15/2023 (Category 2) | Approval End Date | N/A | |
| Modification(s) | 4/10/2023; 5/8/2023 | • | • | |
| Status | Ongoing | | | |

Description: Funded by the federal Office of Child Support Enforcement, this study proposes to bring an existing responsible parenting curriculum to at-risk older youth involved in either the foster care system or the juvenile justice system. The first phase is to evaluate the training curriculum. Individuals must be 18 years or older to participate. Potential subjects will be asked to participate in a self-paced, online training focused on parenting, healthy relationships, financial management, and career/goal planning. The curriculum will also address perceptions about the child support system to dispel any myths or misinformation. The training consists of nine one-hour modules, which participants need to complete within 30 days. Participants will be asked to complete brief online knowledge checks before and after the training. Foster youth will access the training modules online, while juvenile detainees will receive the training in a group

setting.

Potential participants will be referred by key contacts at the VDSS and the Bon Air Juvenile Correctional Center. Participation is voluntary; participants will sign a consent form before starting the study. DSS participants who complete the nine modules will receive total compensation of \$25 in gift cards. DJJ participants will be compensated with commissary credits (225 credits total). The PI anticipates that most participants are English speaking and do not need language services.

No PII will be collected. Participants will be assigned a study ID by the study coordinators at DSS and DJJ. The identifier will be used to track the subject's progress in completing the training modules and to link pre- and post-tests. The key linking participants' names and IDs will be destroyed at the end of the study. Subjects are allowed to skip modules, not answer survey questions, and withdraw from the study at any point. Some topics may be sensitive and trigger emotional or mental distress. If this occurs, the participant will be instructed to contact their study coordinator, who will connect them with services.

The study starts in March 2023 and ends December 2024. DCSE and the VCU Wilder School of Government and Public Affairs will analyze the results. Results will be shared with the federal funder, DJJ, and VDSS Family Services. In the second phase, DCSE will contract a vendor to convert the training into a video game suitable for playing on a portable device.

Modifications: 1) Increase the dollar value of the gift cards offered to DSS subjects; 2) Because the IRB does not have a member on the board who represents the interests of prisoners, DJJ has concerns about the protocol and will not accept the IRB's decision. The PI decided to exclude justice-involved youth from the study. The PI may pursue getting approval from either VCU's IRB or the DJJ research review committee at a later date.

| Project ID | IRB_2023-12 | Submission Date | 2/22/2023 | |
|------------------------|---|------------------------|-----------|--|
| Project Title | MyChildSupport Portal Customer Service Survey | | | |
| | | | T | |
| Submission Type | Initial Review | Review Type | Exempt | |
| Agency Sponsor | N/A | N/A | | |
| Funding | None | | | |
| Investigator(s) | Ezzard (Chuk) Roberts; Matthew Gomez | | | |
| PI Affiliation | VDSS Division of Child Support Enforcement | | | |
| Approved | 2/23/2023 (Category 2) | Approval End Date | N/A | |
| Modification(s) | None | | | |
| Status | Ongoing | | _ | |

Description: The Division of Child Support Enforcement is conducting a survey to solicit feedback from DCSE customers using the MyChild Support web portal. The aim is to improve delivery of child support enforcement services through improvements to the child support web portal and customer service delivery, and improvements or reengineering of specific child support processes. The survey will be administered online, using Qualtrics. When the customer attempts to leave the portal, a pop-up question will appear on the screen asking the customer if they would like to answer a questionnaire. The survey asks the customer about their use of the portal, for example, reasons for accessing the portal, frequency of use, mode of

accessing the portal, and suggested enhancements that would increase use. No personally identifiable information will be collected. The data collection poses minimal risk to subjects.

| Project ID | IRB_2023-13 | Submission Date | 4/4/2023 |
|------------------------|--|--------------------------|----------------|
| Project Title | Analysis of TANF Exit and Spell Patterns using VDSS Administrative | | Administrative |
| | Data | | |
| Submission Type | Initial Review | Review Type | Exempt |
| Agency Sponsor | N/A | | |
| Funding | None | | |
| Investigator(s) | Heeju Jang-Paulsen, PhD; Jiwoo Pierson, PhD | | |
| PI Affiliation | VDSS Office of Research and Planning | | |
| Approved | 4/19/2023 (Category 5) | Approval End Date | N/A |
| Modification(s) | None | | |
| Status | Ongoing | | |

Description: Temporary Assistance for Needy Families (TANF) is a public assistance program designed to provide cash assistance and various technical aids, such as employment services, to promote economic self-sufficiency among low-income families with children. In Virginia, families with at least one work-eligible adult are limited to receiving TANF for 24 months in a single spell and a lifetime limit of 60 months. Once the 24-month time limit is reached, the family is ineligible to receive TANF for another 24 months. While the time limits are in place for various reasons, a typical spell length for TANF and reasons for program exit are not well understood, particularly in the context of the COVID-19 Pandemic, which caused a major social and economic disruption for many low-income families. These elements are crucial in evaluating whether the program is effective in helping Virginians reach self-sufficiency, or how economic hardships may affect families of different backgrounds.

Using client-level administrative records from the TANF case management system (VaCMS), the study will explore TANF spells for two entry cohorts -- clients who entered the program in CY 2018 (pre-COVID) and clients who entered in CY 2020 (during the COVID pandemic). The study will analyze receipt of benefits for 14 months after entry in the program (up to February 2020 and February 2022, respectively, for the first and second cohorts). The study will examine patterns in spell length and likelihood of program exit among TANF recipients to facilitate understanding how effective the current policies are in serving clients in different demographic groups. The study will examine how spell and exit patterns have changed since the onset of pandemic.

In addition to client and case characteristics, the TANF dataset will include information about participation in the TANF work employment program (VIEWS) and identified barriers to employment. The project will also use quarterly earnings from the Virginia Employment Commission (VEC) and unemployment and school closure statistics from publicly available sources (e.g., Bureau of Labor Statistics). The VEC data will be merged with the TANF and the publicly available data for the purposes of this project. Once the datasets have been merged and age variables have been constructed, SSN and date of birth will be deleted from all datasets. All data will be stored on a secure, restricted-access, cloud-based server approved by VDSS IT Security. A waiver of informed consent was approved.

| Project ID | IRB_2023-14 | Submission Date | 4/24/2023 |
|------------------------|--|--------------------------|-----------|
| Project Title | Trauma-Informed Motivational Interviewing Survey | | |
| | | | |
| Submission Type | Initial Review | Review Type | Exempt |
| Agency Sponsor | N/A | | |
| Funding | None | | |
| Investigator(s) | Lauren Weidner; Tiffany Gardner | | |
| PI Affiliation | VDSS Division of Family Services | | |
| Approved | 5/24/2023 (Category 3) | Approval End Date | N/A |
| Modification(s) | None | | |
| Status | Ongoing | | |

Description: The VDSS Division of Family Services contracted with the VCU Center for Evidence-Based Partnerships (CEP-Va) to expand evidence-based services, including adoption of trauma-informed motivational interviewing techniques, to local DSS agencies. CEP-Va and VDSS hired Sage Training and Consulting to deliver the TIMI training to LDSS prevention staff who carry in-home cases as well as their supervisors and local directors.

Sage is using a learning platform, LearnWorlds, to host the 10-week training. Local directors and managers were asked to convey information about the training to their local staff. Supervisors and managers were asked to coordinate enrollment for their staff. Enrollees will create user accounts to access the platform. A series of validated survey instruments will be administered at various points (e.g., Weeks 1 and 10) during the study: 1) Application Potential of Professional Learning Inventory; 2) Helpful Responses Questionnaire: Empathy and MI-consistent responses; and 3) Work Belief Measure: Trauma-Informed Care Belief. Administered through the LMS, the pre- and post- training surveys are used to monitor quality and efficacy of the training and identify areas for improvement for future trainings. Surveys developed by VCU will not be used in this phase of the study until their IRB has approved the project.

The training will be delivered through a mix of pre-recorded and live sessions (three hours per week) hosted on the learning platform. Weeks 1 and 10 will be recorded; weeks 2-9 will be live sessions. The first cohort of 105 employees (broken out into three groups) will start training in April 2023. During Week 1, participants will be asked to complete pre-test surveys. A consent question is embedded in the online surveys. Completion of the surveys is optional and voluntary. To ensure anonymity, participants are asked to create a personal identifier (middle and last initials plus month and day of birth) that will allow Sage to match the pre- and post-test survey responses. Demographic questions will be asked in some of the surveys. Otherwise, no personally identifying information will be collected. Through the platform, participants may inform the trainers if they need learning accommodations. Participants will enter this information in a section of the LMS that will only be viewed by the trainers during the first week. Afterwards, if training participants need further assistance, they are instructed to contact the main trainers.

| Project ID | IRB_2023-20 | Submission Date | 6/23/2023 |
|-----------------|--|------------------------|-----------|
| Project Title | DCSE Paternity Establishment | | |
| | | | |
| Submission Type | Initial Review | Review Type | Exempt |
| Agency Sponsor | VDSS Division of Child Support Enforcement | | |
| Funding | None | | |
| Investigator(s) | Sandra Lamm, PhD; Sarah Smith | , PhD, MPA | |
| PI Affiliation | VDSS Office of Research and Pla | nning | |
| Approved | 6/28/2023 (Category 4) | Approval End Date | N/A |
| Modification(s) | None | | |
| Status | Ongoing | | |

Description: The Division of Child Support Enforcement (DCSE) modified their procedures for establishing paternity. Five DSCE offices (Abingdon, Valley, Central Virginia, Northern Virginia, and Newport News) will pilot the modified procedures for 6 months, starting June 1, 2022. The remaining eight offices served as a control group and continued to use the established procedures.

Using a mix of management reports from the APECS system and client administrative data provided by DCSE, the ORP research team will evaluate the impact of the new procedures on the number of days to administratively establish paternity and the numbers of administrative versus court-established paternities. The research team will assess outcomes occurring during a six-month before the procedural change (December 2021 to May 2022), during the six-month pilot period (June to November 2022), and a three-month period following the end of the pilot (December 2022 to February 2023). To control for office level variables, office administrative data and staffing reports will also be analyzed.

The population for the secondary research study will be cases referred for paternity establishment during the pilot timeframe. A total of 2,833 cases met the study criteria; 2,139 cases were referred to non-pilot offices and 694 cases were referred to pilot offices. Except for case numbers, DCSE stripped all PII information from case data before releasing it to the research team, who do not have direct access to APECS. Case IDs and other identifiers will be stripped from the analysis file. All analysis will be performed on de-identified data. All data will be stored on password protected laptops or on VDSS approved cloud storage. Only Office of Research and Planning research staff will have access to the data.

In another phase of the study (not under review), the researchers will assess case worker job satisfaction and parent client perceptions of DCSE through surveys. Given the variations in implementation fidelity, DCSE is also interested in performing an implementation study to identify any barriers to implementation of the new procedures.

| Project ID | IRB_2023-21 | Submission Date | 6/27/2023 |
|------------------------|---|--------------------------|-----------|
| Project Title | Two-Generational (2Gen) Approach to Promoting Family Well-Being - | | |
| | Pilot | | |
| Submission Type | Initial Review | Review Type | Exempt |
| Agency Sponsor | VDSS Office of Innovation and S | trategic Initiatives | |
| Funding | None | | |
| Investigator(s) | Sarah Smith, PhD, MPA; Ravi R | amcharan | |
| PI Affiliation | VDSS Office of Research and Planning | | |
| Approved | 7/3/2023 (Category 5) | Approval End Date | N/A |
| Modification(s) | None | | |
| Status | Ongoing | | |

Description: The Office of Innovation and Strategic Initiatives (OISI) is spearheading the implementation of two-generational (2Gen) service delivery strategies in seven (7) local departments of social services (LDSS). The 2Gen initiative takes a holistic approach to assessing and addressing family's challenges and need to promote prosperity for all family members. The LDSS will voluntarily incorporate the screening tool, offering mobile social services, and communal roundtables for in-home (family) services and/or TANF-VIEW clients. Participating LDSS offices will choose to implement any of the above-mentioned components into the program of their choice.

The current pilot project under review is an implementation of the screening tool for in-home services for Family Services clients. For each new client enrolling in the in-home program between July 1 and October 31, 2023, caseworkers will complete the 2Gen assessment tool privately after initial interviews. During a 24-month study period, interviews will occur every 3-4 months. The staff will make necessary recommendations to families based on the results of the tool, providing additional resources and opportunities to address any unmet needs of the client or their family members. Use of the 2Gen screening assessment tool will be part of services delivered by case workers. Since clients will not be actively partaking in the data collection process, client consent is not necessary.

Assessment scores and types of referrals made to clients will be recorded in an online (MS) form. No personally identifying information will be collected or stored in the online form. No administrative data will be used in the study. Changes in the assessment scores on each dimension will be tracked periodically over time (every 3 to 4 months for a 24-month study period). In addition, the study will track types of referrals made and whether or not clients followed up on such referrals. The overall implementation feasibility and process will be assessed through focus groups with participating LDSS caseworkers after 3 months of incorporating the 2Gen screening tool. Focus group meetings will be virtual and recorded. Meeting transcriptions will be stripped of any identifiable data. Case workers and their supervisors will not participate in the same focus group meetings. Case workers will be asked about the process of using the 2Gen screening tool, not about individual clients.

Appendix H: Approved Study Modifications/Continuations, SFY 2023

In addition to new FY 2023 studies previously mentioned that also requested approval of modifications, here are additional older studies that requested approval of changes and/or continuations.

| Project ID | IRB_2019-20 | Submission Date | 8/31/2022 |
|------------------------|-----------------------------------|--------------------------|----------------|
| Project Title | Virginia Infant Toddler Support 1 | | d Early |
| | Childhood Mental Health (ECMI | \mathbf{H}) | |
| Submission Type | Modification / Continuing | Review Type | Expedited |
| Agency Sponsor | VDSS Child Care & Early Childle | * ' | * |
| Funding | US Dept. of Health & Human Ser | rvices (RFA # OECD-17 | 7-052) to VDOE |
| Investigator(s) | Amy Stutt, M.Ed | | |
| PI Affiliation | Child Development Resources | | |
| Approved | 8/31/2022 | Approval End Date | 8/31/2023 |
| Modification(s) | 9/1/2022; 10/31/2022 | | |
| Status | Continuing | | |

Description: This expands upon activities started by the Virginia Infant Toddler Specialist Network (VA-ITSN) under previous grants in 2019. Through a coordinated system of care, the project provides mental health services and education to families of infants and toddlers and professional training to caregivers and early childcare teachers and directors. The training focuses on fostering nurturing and responsive relationships between caregiver and child; building social skills, emotional regulation and problem solving with guidance and coaching; and providing interventions for children with persistent challenging behaviors. The goal is to enhance the social-emotional development of infants and toddlers, especially those at risk or displaying challenging behaviors, while in care away from parents and to assist families in using community services and supports.

Modifications: The following changes were approved:

- 1) To decrease the number of forms for participants, several were combined. The Child Specific Observation Scale was added.
- 2) Under a new RFA, the study's sponsor/funder is now the Virginia Department of Education, and the sponsor's main contact is Arlene Kasper.
- 3) The program component ITMH (Infant Toddler Mental Health) has been renamed to ITBC (Infant Toddler Behavioral Consultation). Numerous forms have been amended to reflect the program's new name change. Five other forms will no longer be used.
- 4) Changes to the steps of providing ITBC coaching services to classrooms based on CLASS and TPITOS scores. Changes to the steps of providing ITBC coaching services to children based on assessments using the CHAT R/F, TPITOS, ASQ screenings, etc. Option to use the PICCOLO during coaching sessions.
- 5) Change the record retention process: Documents will be saved at either regional offices or home office (CDR). Hard copy records will be destroyed after saved in electronic format. No confidential data may be stored on a desktop computer, laptop, or removable media.
- 6) Use the Infant and Toddler CLASS assessment tools with child care programs receiving coaching.
- 7) Provide coaching, training, and TA services virtually as needed by providers. Include TA as a service provided to child care programs as needed.

| Project ID | IRB_2022-05 | Submission Date | 6/22/2023 |
|------------|-------------|------------------------|-----------|

| Project Title | Virginia Infant Toddler Support Network (VA-ITSN) and Early Vi | | | |
|-----------------|---|----------------------------------|-----------|--|
| | Childhood Mental Health (ECMH) | | | |
| Submission Type | Modification Review Type Expedited | | | |
| Agency Sponsor | None | | | |
| Funding | U.S. Department of Education, Office of Safe and Supportive Schools | | | |
| Investigator(s) | Jessica Marcon Zabecki, PhD | | | |
| PI Affiliation | Virginia Department of Education | Virginia Department of Education | | |
| Approved | 6/23/2023 | Approval End Date | 8/31/2023 | |
| Modification(s) | 6/26/2023 | | | |
| Status | Continuing | | | |

Description: School-based mental health professionals and division and school administrators in seven school divisions in Virginia will be invited to participate in a survey about their ability to offer mental health services virtually ("mental telehealth") and any perceived successes and barriers to implementation. School-based mental health providers will also be asked about job satisfaction, burnout, turnover intentions, workplace loneliness and commitment to their agency.

Subjects will review the consent language on the first page of the online survey. No personally identifiable information will be collected.

Modifications: 1) The primary investigator changed from Dr. Zabecki to Mr. Casper Sturm. Dr. Zabecki is leaving VDOE and transferring responsibility of the School Mental Health project to Mr. Sturm.

2) The project will be using Qualtrics instead of SurveyMonkey to collect survey responses. Any materials (e.g., Consent Form, recruitment email messages) that mention the former PI and the survey platform have been modified to reflect the new changes.

| Project ID | IRB_2022-07 | Submission Date | 1/31/2023 | |
|------------------------|---|--|-----------|--|
| Project Title | PJAC Research Supplement | | Vi | |
| | | | gi | |
| Submission Type | Continuation | Review Type | Expedited | |
| Agency Sponsor | VDSS Division of Child Suppor | VDSS Division of Child Support Enforcement | | |
| Funding | U.S. Department of Education, Office of Safe and Supportive Schools | | | |
| Investigator(s) | Melanie Skemer, MA | | | |
| PI Affiliation | MDRC | MDRC | | |
| Approved | 2/7/2023 | Approval End Date | 9/30/2023 | |
| Modification(s) | 8/5/2022; 11/18/2022 | | | |
| Status | Continuing | | | |

Description: The PJAC (Procedural Justice-Alternative to Contempt) demonstration tested the efficacy of incorporating procedural justice principles into child support enforcement practices as an alternative to contempt in six states, including Virginia. MDRC assessed the effects of the PJAC intervention, as well as its implementation and costs ("core study"). This new study builds on the core study by using state agency records (from APECS) and project data from the original study to assess biases in the use of punitive enforcement actions, the impact of COVID-19 on child support program operations and families, and the optimal targeting of PJAC-like services.

This study examines agency interactions with custodial and non-custodial parents from approximately 300,000 cases active between January 2019 and December 2021 and the services provided to those families during the three-year period. DCSE will share program data that includes case ID for matching; no other PII will be included in any of the data files sent to MDRC. Other variables from the administrative system will be included in the data request.

The study will also involve interviewing parents, staff, and partners from the original study as well as new staff, partners and parents who have an active case.

Modifications:

- 1) The study will conduct semi-structured interviews with former PJAC program managers and current child support staff to inquire about new and ongoing PJAC-related activities. On-site coordinators will be recruited.
- 2) The study will conduct a new round of interviews with PJAC staff, partners, and parents. Parents will be given a \$40 gift card for their participation. These interviews will be used to document and understand how the COVID pandemic affected child support operations and families. Onsite coordinators will assist with recruitment and obtain permission from parents to release their contact.
- 3) Waiver of documentation of informed consent for staff and parent interviewees was approved. The study will provide parents and staff an information sheet (or it will be read to them) that includes consent language.
- 4) Interview protocols for both parent and staff/partner interviews were submitted. With permission from the interviewee, only the audio portion of the interviews will be recorded for note-taking purposes.

| Project ID | IRB_2020-04 | Submission Date | 11/4/2022 |
|------------------------|---|--------------------------|------------|
| Project Title | Credit Check Program Evaluation | | Vi |
| | | | gi |
| Submission Type | Continuation / Modification | Review Type | Expedited |
| Agency Sponsor | VDSS Division of Child Support Enforcement | | |
| Funding | U.S. Department of Education, Office of Safe and Supportive Schools | | |
| Investigator(s) | John Gyourko | | |
| PI Affiliation | VDSS Division of Family Service | ces | |
| Approved | 11/7/2022 | Approval End Date | 12/31/2024 |
| Modification(s) | 11/7/2022 | | |
| Status | Continuing | | |

Description: In an exploratory study reviewed and approved in 2019, this project uses VDSS credit check program records in addition to client and case information from OASIS (e.g., demographics, foster care history and placements, sex trafficking history) to determine if there is a correlation with discovered credit report issues. The credit report information is already deidentified.

Modifications: In the original proposal, administrative foster care data and credit check program records from October 2015 to June 2019 would be linked to examine credit check outcomes. All PII except client ID would be removed. The PI is requesting a continuation to expand upon the original study by adding more credit record data (through December 2021) to do more extensive analyses for his doctoral dissertation. The PI will be using logistic regression modeling rather than bivariate analyses to examine a relationship between demographic and foster care placement factors and identity fraud victimization. In addition, the PI will examine the impact of the COVID-19 pandemic occurring in 2020 and 2021 on credit check outcomes.

| Project ID | IRB_2022-11 | Submission Date | 6/13/2023 |
|------------------------|--|--------------------------|----------------|
| Project Title | A Randomized Trial of the Effects of SNAP Work Requirement | | |
| | Waivers on Program Participation | on, Labor Supply, and | Well-being gir |
| Submission Type | Continuation | Review Type | Expedited |
| Agency Sponsor | None | | |
| Funding | Abdul Latif Jameel Poverty Action Lab | | |
| Investigator(s) | Heeju Jang-Paulsen, PhD; Adam Leive, PhD (UC-Berkeley) | | |
| PI Affiliation | VDSS Office of Research and Planning | | |
| Approved | 6/15/2023 | Approval End Date | 6/15/2024 |
| Modification(s) | N/A | | |
| Status | Continuing | | |

Description: SNAP clients who are able-bodied and without dependents (ABAWDS) are required to work and engage in other related activities to remain eligible for the program. Each year, the state receives a set number of monthly work requirement exemptions to allocate to clients at its discretion. The number of exemptions is far less than meets the need of all clients. The purpose of this study is to assess how exemptions affect program participation, labor supply (future employment), and well-being across various groups. The goal is to have DSS better allocate future exemptions to meet program goals.

Approximately 40,000 SNAP clients, who enrolled or re-certified between March and June 2022 will participate in the study. In Phase I, we will randomize SNAP ABAWD clients who are subject to time-limited benefits (unless they meet work requirements) to either a control group or one of four treatment groups; the first and second treatment groups will have work requirements waived, respectively, for six or for 12 months; the third and fourth groups will have program recertification extended by six months or 12 months, respectively. Clients will be passively enrolled in the study (waiver of informed consent was approved). The administrative changes and subject random assignment will occur in VaCMS.

Using program data from VaCMS and quarterly earnings data from the Virginia Employment Commission, the study will track, respectively, SNAP participation and employment up to 3 years. The linked datasets will be deidentified and sent to the UVA and Harvard research teams for data analysis.

In Phase 2, SSRS, a partner research firm, will conduct a survey a sample (5,000) of study participants to assess their well-being. Participants may complete the survey online, through a telephone interview, or mail a printed copy. The study will offer a small monetary incentive for participation. The consent language will be included in the survey letter or invitation. introduction. The survey responses will be merged with the rest of the study data by using the client's VaCMS ID.

The study has not started due to work requirements and recertification rules being relaxed during the COVID-19 public health emergency. Consequently, the study requested a continuance into 2024.