

Danny TK Avula MD, MPH Commissioner

November 16, 2022

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 submitted in compliance with § 63.2-218 of the Code of Virginia, which states:

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

If you have questions, please feel free to contact me at (804) 726-7011.

DA:kc Attachment

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

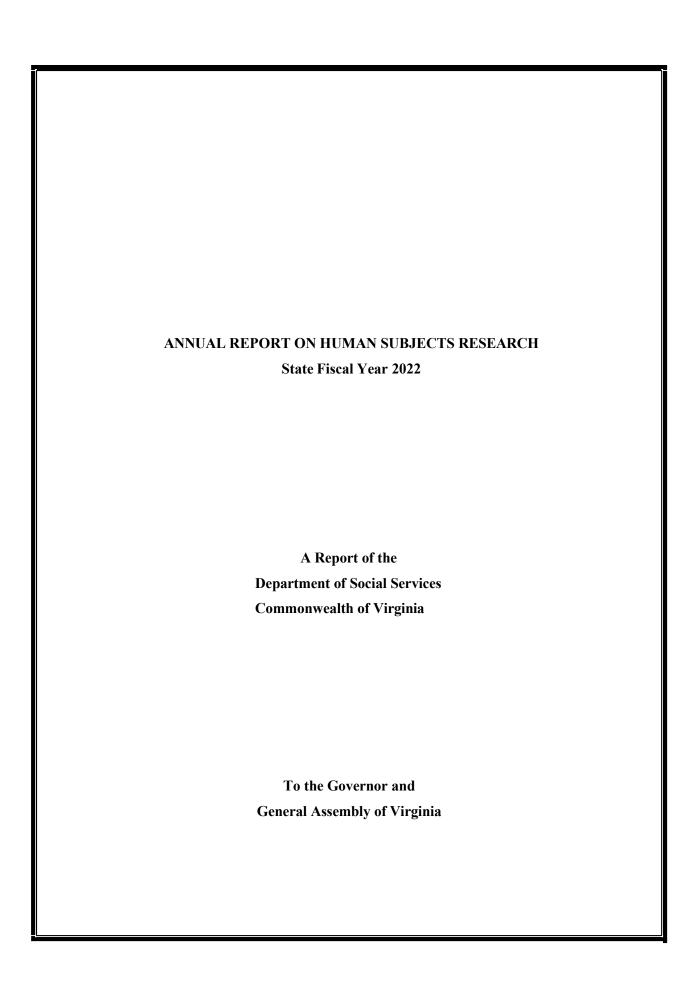


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EXECUTIVE SUMMARY

REPORT MANDATE

Section <u>63.2-218</u> of the Code of Virginia requires the Virginia Department of Social Services (VDSS) human research committee to submit to the Governor, the General Assembly, and the Commissioner an annual report on the human research projects reviewed and approved by the committee. The Code also requires the human research committee to report any significant deviations from the proposals as approved.

BACKGROUND

The VDSS human research committee, known as the Institutional Review Board (IRB), ensures research will be conducted in compliance with federal (45 CFR 46 et seq.) and state (§32.1-162 and 22VAC40-890 et seq.) statutes. The IRB reviews, approves, and monitors research conducted or authorized by VDSS, local departments of social services (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 2022

Change in IRB Leadership and Membership

The IRB membership changed extensively in SFY 2022. The chairperson role transitioned from Dr. Eleanor Brown to Dr. Gail Jennings upon Dr. Brown's retirement in December 2021. Dr. Danny Avula was appointed by Governor Youngkin to be the new Commissioner of the Virginia Department of Social Services in January 2022. The Commissioner serves as the Signatory Official for any research conducted by the agency. Furthermore, the IRB recruited six additional members to increase its diversity in terms of demographics and subject matter expertise. A list of the IRB members is included in the appendices.

Board Meetings

The VDSS IRB met virtually on April 21, 2022, thus fulfilling the Commonwealth's regulation that the IRB meet at least once annually. The meeting minutes are included in the appendices.

Studies Approved

A summary of each study submitted and reviewed by the VDSS IRB in SFY2022 are described in more detail in the appendices. We briefly summarize them here.

- The VDSS IRB did not receive, review or approve any studies requiring full board review, as no studies submitted posed more than minimum risk to participants under state and federal codes (respectively, 22VAC40-890 and 45CFR46).
- The IRB reviewed and approved seven (7) projects, multiple modifications to an existing research project, and one continuation of an existing research project under Expedited Review procedures described in 22VAC40-890 and 45CFR46. While these procedures include a review of all elements required of a full Board Review, only two IRB members (including the Acting Chairperson) are required to conduct the review.
- Four (4) research projects were deemed Exempt from IRB Review, under conditions described in 22VAC40-890 and 45CFR46.

CONCLUSION

All research approved by the IRB in SFY 2022 satisfied the regulatory definition of minimal risk and involved activities such as surveys, interviews, program evaluations, or use of administrative data. There were significantly more studies submitted, reviewed, and approved by the VDSS IRB in SFY 2022, compared to SFY 2021 when the Commonwealth was experiencing the early stages of the COVID-19 Public Health Emergency. Priorities for SFY 2023 are as follows:

- Work with the Office of the Attorney General to revise certain sections of the state Code (e.g., 22VAC40-890-30, 22VAC40-890-80) 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.
- Promote use of the <u>Collaborative Institutional Training Initiative (CITI)</u> training platform for VDSS and LDSS staff who are involved in departmental research; continue to provide this training opportunity to new and continuing IRB members.
- Increase awareness of human subjects research protections among VDSS staff who use Qualtrics.XM, the agency-supported cloud-based, online survey tool, for data collection.
- Streamline VDSS IRB procedures and forms; investigate developing electronic submission forms.

- Set up a Microsoft Teams site to facilitate IRB communication and meetings.
- Make updates to the content of the <u>VDSS IRB website</u>, as necessary.

FY 2022 ANNUAL REPORT ON HUMAN SUBJECTS RESEARCH By the VDSS INSTITUTIONAL REVIEW BOARD

REPORT MANDATE

Section <u>63.2-218</u> of the Code of Virginia requires the Virginia Department of Social Services (VDSS) human research committee to submit to the Governor, the General Assembly, and the Commissioner at least annually a report on the human research projects reviewed and approved by the committee. The Code also requires the human research committee to report any significant deviations from the proposals as approved. This report documents State Fiscal Year (SFY) 2022 activities of the VDSS human research committee, known as the Institutional Review Board (IRB).

BACKGROUND

The 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 criteria for being exempt from review, 2) is appropriate for expedited review, or 3) requires full board review. Generally, two IRB members (or the Chair and another member) conduct exemption determinations and expedited reviews. 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 IRB reviews social-behavioral studies, not clinical or animal studies. Many of these studies entail evaluation of delivery of program services and/or benefits to agency clients. Risk of physical harm is unlikely for these types of studies or evaluations. Most reviewed studies qualify as minimal risk. The potential harm associated with a minimal risk study include possible violations of privacy and confidentiality, inequitable treatment, coercion and lack of informed consent by the client, and, to a lesser

extent, the 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 Institutional Review Board (IRB) provided for in its assurance filed with the Office of Human Research Protections and will be subject to continuing review by the IRB. The IRB is responsible for providing guidance and oversight for the human research protection program and for helping to maintain compliance with applicable laws, regulations, and policies.

The IRB is responsible for the following oversight functions:

- 1. Determine what activities constitute human participant research.
- 2. Review and determine if all research activities comply with this policy prior to the commencement of the research. In cases of approval with conditions, require investigators to make modifications to the study prior 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.
- 7. Suspend or terminate approval of research not conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and will be reported promptly to the investigator and appropriate institutional official.
- 8. Obtain reports summarizing the findings of completed studies and publish them on the VDSS public website.

IRB ACTIVITIES IN SFY 2022

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 U.S. Office for Human Research Protections (OHRP) was updated on 4/15/2022; the assurance is effective through 4/15/2027. In addition, the VDSS IRB's registration (#IORG0004422) with OHRP was 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 Leadership and Membership

The VDSS Office of Research and Planning (ORP) is responsible for administering the IRB and ensuring compliance with federal and state regulations regarding human subject research. Dr. Jeff Price, VDSS ORP Director, serves as the agency's Data Ombudsman and has general oversight over IRB activities. Dr. Price regularly attends IRB meetings and serves as an alternate voting member, if a quorum is not attained.

Typically, a policy analyst (Research Associate Senior) from ORP, chosen by Dr. Price and appointed by the Commissioner, takes the lead on coordination of IRB activities as well as chairing the IRB meetings. All IRB-related inquiries are submitted to irb@dss.virginia.gov, which goes to the email inbox of the designated IRB Chair and Coordinator.

Several changes to the IRB leadership and membership occurred mid-way through SFY 2022. First, the IRB chairperson role transitioned from Dr. Eleanor Brown to Dr. Gail Jennings upon Dr. Brown's retirement from the agency in December 2021. As Chair, Dr. Jennings also coordinates all IRB activities, including assigning application reviews to members and facilitating changes to IRB protocol and procedures. Second, Dr. Danny Avula was appointed by Virginia Governor Youngkin to be the new

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¹ Dr. Gail Jennings, a long-standing member of the Board since 2012, has previously served as the appointed chairperson and coordinator from 2012 to 2015 and served as acting chair in 2017-2018, before Dr. Brown joined the Board in late 2018. For this cycle, Dr. Jennings has agreed to serve in the interim as the IRB Chair and

Commissioner of the Virginia Department of Social Services, effective in January 2022. The Commissioner is recognized as the Signatory Official for any research activities conducted or supported by the agency.

Third, the IRB recruited six additional members to increase its number and diversity in terms of demographic background and subject matter expertise. Six members from the 2019-2021 term were reappointed for another 3-year term (SFY 2022-2024), while three other members left the IRB. To fill the vacant positions, Dr. Jennings recruited two new members—Dr. Jennifer Piver-Renna of the Virginia Department of Education and Dr. Jamie Cage of the Virginia Commonwealth University – in December 2021. Recognizing that the IRB lacked gender diversity, Dr. Jennings recruited four additional new members in June 2022: Dr. Dev Nair (Virginia Department of Behavioral Health and Developmental Services), Christopher Campbell (Virginia Home for Boys and Girls), Tim Reddish (Commonwealth Catholic Charities), and Stephen Wade (VDSS).

Aside from increasing the number of men on the IRB, two new members (Mr. Reddish and Mr. Campbell) have social work degrees and currently work with at-risk children and families, thus bringing the perspective of direct service providers. Mr. Wade has been involved in projects focused on substance abuse and is currently the health equity manager for VDSS. Dr. Nair comes to the IRB with previous experience leading the IRB at the Virginia Department of Health and brings a needed perspective on clients with intellectual disabilities in his current role as Assistant Commissioner for DBHDS. Dr. Cage, an assistant professor in the VCU School of Social Work, participates in research on children in foster care and, as an investigator, has previously used DSS client administrative data. Dr. Piver-Renna, who is director of research at VDOE, provides a perspective on education and early child care studies. VDOE is in the midst of establishing its own human research review committee, and Dr. Piver-Renna will take this opportunity to learn about IRB operations.

As listed in Appendix A, the IRB now consists of eleven (11) voting members, including the IRB Chairperson/Coordinator, plus Dr. Price. Each member of the IRB was recently appointed by the new VDSS Commissioner to serve a three-year term, through June 30, 2024. The VDSS IRB complies with all state and federal human research regulations regarding its composition.

Coordinator until a new ORP staff member can assume these duties.

Board Meetings

In fulfillment of state regulations, the acting VDSS IRB Chairperson convened the IRB on April 21, 2022. The meeting took place virtually via Google Meeting. (Due to continuation of the COVID-19 public health emergency, the Chair suspended in-person meetings for the time being.) Eight of nine members, who were appointed in December 2021, attended the meeting. The Chair introduced the two new appointees from December 2021: Drs. Jennifer Piver-Renna and Jamie Cage. One of the members presented a study recently approved under expedited review. The IRB members discussed other business matters, including use of the CITI training platform, member recruitment, and revisions of the state IRB regulations. Appendix B shows a copy of the April 21 meeting minutes.

Based on the consensus of the group, the IRB members agreed to hold an annual convening; members will attend ad-hoc meetings to discuss emergent issues (e.g., carry out full board reviews). The next meeting will be held in Fall 2022. Furthermore, the members agreed to use e-mail for communication of IRB-related business. The Acting Chair will explore using a Microsoft Teams site for exchanging information, document sharing, and scheduling meetings.

Approved Studies

Any study that has activities that pose more than a minimal risk to subjects or do not fall within the categories approved for expedited review procedures need a review and approval by the full board. No studies qualified for a full board review in SFY 2022.

There were significantly more studies submitted, reviewed, and approved by the VDSS IRB in SFY 2022, compared to SFY 2021 when the Commonwealth was experiencing the early stages of the COVID-19 Public Health Emergency.

- The IRB reviewed and approved seven (7) new projects under expedited procedures, as described in 45 CFR 46. Under expedited review, only two members of the Board, including the Chair, are required to review the study. Refer to Appendix C for a brief description of each study.
- In addition, one already approved study requested approval of multiple modifications to its
 protocol, and another study requested a continuance of the project (refer to Appendix D). The
 latter study had concluded its data collection activities as of September 2020 and was conducting
 data analysis.
- Four (4) research projects were deemed Exempt from IRB Review, under conditions described in 45 CFR 46. Refer to Appendix E.

CONCLUSION

All research approved by the IRB in SFY 2022 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 2023:

- Work with the Office of the Attorney General to revise certain sections of the Virginia
 Administrative Code (e.g., 22VAC40-890-30, 22VAC40-890-80) 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.
- Promote use of the <u>Collaborative Institutional Training Initiative (CITI)</u> training platform for VDSS and LDSS staff who are involved in departmental research; continue to provide this training opportunity to new and continuing IRB members.
- Increase awareness of human subject research protections among VDSS staff who use Qualtrics.XM, the agency-supported cloud-based, online survey tool, for data collection.
- Streamline VDSS IRB procedures and forms; investigate developing electronic submission forms.
- Set up a Microsoft Teams site to facilitate IRB communication and meetings.
- Make updates to the content of the <u>VDSS IRB website</u>, as necessary.

APPENDIX A: VDSS IRB MEMBERSHIP FOR SFY 2022-2024 (AS OF 6/30/2022)

IRB Role	Name	Agency	Title
Chair & Administrator (Acting)	Gail C. Jennings, PhD	Virginia Department of Social Services, Office of Research and Planning	Senior Research Associate
Member	Dhara Amin, PhD	Virginia Department of Juvenile Justice	Research Analyst & Coordinator – Ext. Research
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	Virginia Department of Social Services, Division of Information 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	Virginia Department of Social Services, Division of Family Services	Assistant Director, Policies & Practice
Member	Jennifer Piver-Renna, PhD	Virginia Department of Education, Office of Research	Director
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	Virginia Department of Social Services, Community and Volunteer Services	Health Equity Project Manager
Ombudsman; Alternate	Jeff Price, PhD	Virginia Department of Social Services, Office of Research and Planning	Division Director

APPENDIX B: VDSS IRB MEETING MINUTES – APRIL 21, 2022

DATE: Thursday, April 21, 2022

TIME: 11:00 am to 12:00 pm (Adjourned at 11:47 am)

LOCATION: Virtual (the meeting was not audio recorded)

MEMBERS PRESENT: Gail Jennings (Acting Chair, VDSS), Dhara Amin (DJJ), Jamie Cage (VCU), Mary Disse (VDSS), Em Parente (VDSS), Jen Piver-Renna (VDOE), Jeff Price (VDSS), Tamara Temoney-Porter (Hampton DSS). <u>Absent</u>: Carolyn Hawley (VCU).

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

Introduction of New Members

Dr. Jamie Cage, Assistant Professor in the VCU School of Social Work, and Dr. Jennifer Piver-Renna, Director of Office of Research at the Virginia Department of Education, were appointed as new members in December 2021.

Dr. Eleanor Brown, who served as the IRB Chair from 2018-2021, retired in early December. Hayley Cleary and Traci Pike chose not to renew their terms as members. Em Parente, Mary Disse, Tamara Temoney-Porter, Dhara Amin and Jeff Price were each reappointed in December for a 3-year term ending June 2024. The roster of IRB members is posted on the VDSS IRB web page. Please let me know if any corrections are needed.

Announcements

The Annual Report on Human Subjects Research for SFY 2021 was submitted to the Virginia General Assembly last Fall. The report is posted on the IRB web page.

Since Fall, the Office of Research and Planning has been recruiting to fill several vacancies in its unit. One new hire started in February; another new hire will start in late May. We hope to fill two additional vacancies. For now, I will continue to serve as the Acting Chair and Coordinator of the IRB until we have identified a new replacement among the new hires.

The Chair reminded members to complete IRB training through CITI and/or submit training certifications. Em Parente asked about the timing of refresher training in CITI. For IRB members, the certification for completion of the Basic HSR (Human Subjects Research) modules expires three years after completing the course. The refresher training is good for four years. I recall receiving an email notification to complete the refresher course after my Basic HSR certificate expired (or was close to expiring). It is not necessary to complete any IRB training on an annual basis. If you are not sure which training you completed and what is due, please contact the Chair.

State codes relevant to the IRB -- 22VAC40-890 (Human Subject Research Regulations) and 22VAC40-910 (Maintaining & Disclosing Confidential Information of Public Assistance, Child Support Enforcement and Social Services Records) – require periodic review and revision, if necessary. Consulting with the OAG, the former Chair (Dr. Eleanor Brown) drafted a version with minor wording changes to subsections (e.g., Definitions) in 22VAC40-890. TH-04 is ready to be submitted for a Fast Track review (see attached "Chart - Fast Track Regulations").

Dr. Brown also indicated a need to make extensive changes to subsection 890-80 (Expedited Review) to align it with current federal regulations (45CFR46 – 2018 Common Rule or "2018 Requirements"). Recently, Dr. Jennings identified a similar need to make changes to 890-30 (Research Exempt from Chapter). She has contacted the OAG to start preparing a draft of the changes. Em Parente offered staff support (Nikki Callaghan) to help the Office of Research and Planning prepare the Town Hall documents (TH-04). Dhara Amin from DJJ also offered her support.

FULL BOARD REVIEW

No studies were submitted that required a full board review.

REPORT OF OTHER REVIEWS AND APPROVALS (SFY2020 TO DATE)

- ***** Expedited Reviews (6)
 - TANF Data Collaborative Client Survey (#IRB-2022-01)
 - HEALS Knowledge, Utilization, & Uptake Survey (#IRB-2022-04)
 - DOE Recruiting and Retaining Virginia School Mental Health Providers Study (#IRB-2022-05)
 - Healthy Families Visiting Survey 2021 (#IRB-2022-06)
 - PJAC Supplemental Research Study (#IRB-2022-07)
 - Digital Literacy and TANF Work Programs (#IRB_2022-12) Jen presented a thorough description of the study, including recommended changes to the recruitment and consent process.

The Chair mentioned that the PI is a doctoral student completing this study for her dissertation. Dhara Amin raised concerns about new investigators submitting IRB applications with consent forms missing key elements and not complying with current federal regulations. We discussed what role the IRB should play in catching these errors.

- **❖** Modification(s)
 - Virginia ITSN & ECMH Study (#IRB-2019-20) Modifications #2 and #3
- Continuation(s)
 - DCSE-PJAC Study (#IRB-2018-06)
- **Exempt from Review (4)**
 - Licensing Assisted Living Facility Infection Control Survey (#IRB-2022-03)
 - Kinship, Foster, and Adoptive Family Survey (#IRB-2022-08)
 - CFSR Systemic Factors Survey (#IRB-2022-09)
 - UVA Child Care Subsidy Study (#RIB-2022-10)

For more details, refer to the "Summary of Projects Submitted for IRB Review – SFY 2022" attachment.

In Process

SNAP Work Requirements RCT Study (#IRB-2022-11) – Because the Chair has been involved in the planning meetings for this project, she must excuse herself from any review of the project. She asked for two volunteers to review this study. Tamara Temoney-Porter volunteered to serve as a reviewer. The Chair will send an email announcement soliciting another volunteer after the meeting. The Chair agreed to allow reviews to be completed within 14-21 days. Both reviews should be completed and submitted to the Chair by Friday, May 13.

NEW BUSINESS

Member Recruitment – The Chair pointed out that the Board, which has eight voting members plus a non-voting member (Jeff Price), is not diverse in terms of gender (8 women, 1 man). The Chair also indicated that the Board needs more non-scientific members (e.g., clergy, legal) to serve. The Chair is seeking names of potential candidates to serve as members.

Proposed Next Meeting: By majority vote (8-0), the Board decided to meet annually, unless a full board review requires scheduling an ad hoc meeting. State and federal code and regulations state that the Board needs to meet at a minimum of once yearly. The regulations do not state whether or not meetings must be held in-person. We will continue to schedule virtual meetings if this is most convenient for members.

The next meeting will be scheduled in Fall 2022. The Chair will send a Doodle poll in early September to select the best date.

Action Item	Lead(s)	Deadline
Volunteer to review the SNAP Work Requirements Study (need two people)	ALL	4/22/2022
Complete CITI IRB Training (Basic HSR-SBE modules or Refresher) or provide evidence of other training	ALL	9/30/2022
Recommend individuals to serve on the VDSS IRB whom the Chair can contact (need more representation from lay/non-scientific community)	ALL	Ongoing

ADJOURNED TIME: 11:47 AM

ATTACHMENTS:

Chart – Fast Track Regulations
 Summary of Projects Submitted for IRB Review – SFY 2022

APPENDIX C: STUDIES APPROVED BY EXPEDITED REVIEW PROCEDURES, SFY 2022

Project ID	IRB_2022-01
Project Title	TANF/VIEW Exit Survey
Type of Submission	Initial Review
Type of Review	Expedited under 45 CFR 46
Agency Sponsor	VDSS Division of Benefit Programs (TANF)
Funding (if applicable)	None
Principal Investigator(s)	Heeju Jang-Paulsen, PhD
PI Affiliation	VDSS Office of Research & Planning
Approved	7/16/2021
Modification	7/23/2021
Date Approval Ends	7/16/2022
Status	Completed

Description: The aim is to assess the experiences of former TANF/VIEW enrollees while in the program and after leaving the program, especially participation in the labor force. Through an online survey, former participants were asked about the program components in which they participated that may have contributed to improving their employment outcomes. In addition, the survey asked about the extent to which they were aware of the benefit cliff (a relatively small increase in earnings resulting in a loss of benefits worth far more than the increase in income), and whether it served as a disincentive to work. Finally, the survey asked how they did financially nine months after leaving TANF/VIEW. The survey link was sent via email, text message, and postal mail to approximately 2,500 adult case leads who had left VIEW in CY 2019 and part of 2020. Participants were offered a \$25 Visa gift card as an incentive to complete the survey. If interested, participants opted into completing a separate raffle entry form. Other than the raffle entry form, the survey did not collect any personally identifiable information. Information entered on the raffle entry form could not be linked back to participants' responses on the main survey.

The modification, which was approved on 7/23/2021, involved mailing an abbreviated, easier to type survey URL (created in TinyURL.com) to a subset of participants. In addition, the survey deadline was extended to August 10 to increase the response rate.

Project ID	IRB_2022-04
Project Title	Knowledge, Utilization, and UpTake (KUUT) of the Virginia HEALS Toolkit
Type of Submission	Initial Review
Type of Review	Expedited under 45 CFR 46
Agency Sponsor	VDSS Division of Family Services
Funding (if applicable)	None
Principal Investigator(s)	Laurie Crawford, MPA
PI Affiliation	Division of Family Services, Family Violence Program
Approved	11/4/2021
Modification	None
Date Approval Ends	11/4/2022
Status	Completed

Description: Between October 2020 and July 2021, staff at the Virginia Department of Social Services (VDSS) conducted 47 HEALS trainings for over 1,200 providers at partner child, youth, and family service agencies. HEALS, which stands for "Helping Everyone Access Linked Systems", is a Trauma-Informed Model of Service Delivery. The accompanying toolkit provides information and resources that promotes the implementation of policies, practices, and procedures for identifying children who have experienced trauma and providing them coordinated support based on their individual needs and identities.

The Knowledge, Utilization, and Uptake (KUUT) Survey was administered online to the HEALS training participants during the latter part of 2021. The purpose of the KUUT Survey was to assess the providers' awareness, knowledge, and current (or intended future) use of the HEALS toolkit. Survey participants were recruited by email.

Study information was documented on the first page of the survey. Study participants provide informed consent by opting into completing the rest of the survey. Survey respondents were offered a chance to win a \$10 Target gift card (1-in-50 chance). The raffle entry form was separate from the main survey. No personally identifiable information was collected in the main KUUT Survey.

After the project closed in December 2021. Based on responses from 169 service providers from various agencies and systems, most indicated that they have accessed or plan to access the Toolkit, that the Toolkit material was easy to understand, and that they have either partially or fully implemented resources within it.

Project ID	IRB_2022-05
Project Title	Recruiting and Retaining Virginia School Mental Health Providers: Evaluating the impact of grant funded activities
Type of Submission	Initial Review
Type of Review	Expedited under 45 CFR 46
Agency Sponsor	Virginia Department of Education
Funding (if applicable)	U.S. Department of Education, Office of Safe and Supportive Schools
Principal Investigator(s)	Jessica Marcon-Zabecki, PhD; Jennifer Piver-Renna, PhD
PI Affiliation	Virginia Department of Education
Approved	9/3/2021
Modification	None.
Approval Ends	
Status	In progress

Description: School-based mental health professionals and division and school administrators were invited to complete an online survey as part of a grant-funded evaluation of school mental health programs and recruitment and retention strategies for school mental health providers. The survey asks participants for feedback about telehealth services focused on mental health, mental health programming, perceived successes and barriers to implementing mental health programs for students. School-based mental health providers were asked about their job-related experiences such as satisfaction, employee burnout, intent to leave (turnover), workplace loneliness, barriers to service provision, perceived effectiveness of program activities, and professional development.

The study population is 350 school-based mental health workers (e.g., school counselors, school psychologists, school social workers) and an estimated 250 school administrators from seven school divisions across the state (Chesapeake City Public Schools, Danville City Public Schools, Henry County Public Schools, Petersburg City Public Schools, Suffolk City Public Schools, Washington County Public Schools.). Participants were recruited from members subscribing to an existing listserv maintained by the VDOE Office of Student Services. In addition, VDOE advertised the study to division and school leadership through a Superintendent's Email. Informed consent was obtained prior to opening the survey. No personally identifiable information was collected in the survey.

Project ID	IRB_2022-06
Project Title	Healthy Families Virginia Home Visitation Surveys
Type of Submission	Initial Request
Type of Review	Expedited under 45 CFR 46
Agency Sponsor	VDSS Division of Family Services
Funding (if applicable)	None
Principal Investigator(s)	Aline Jesus Rafi, PhD; Heeju Jang-Paulsen, PhD
PI Affiliation	VDSS Office of Research and Planning
Approved	7/28/2021
Modification	None
Approval Ends	7/28/2022
Status	Completed

Description: Since the COVID-19 lockdown in March 2020, the Healthy Families Virginia (HFV) program has been delivering its home visitation program virtually. The Virginia Department of Social Services (VDSS) is interested in researching how effective virtual visiting has been in the past year. Specifically, VDSS seeks to understand the perspectives of participating families and of home visitors: their experience in transitioning to virtual visitation, satisfaction with the new delivery format, and opinions on returning to in- person visitation.

Separate surveys were sent to participating families (those who had at least 3 in-person home visits prior to March 2020 and continued home visits virtually in 2020/2021) and to home visiting staff (home visitors and dual role supervisors) involved in their cases. A Spanish version was available for families who speak primarily Spanish. The survey was designed and administered through Qualtrics.

At least 150 families and 50 home visitors were offered a \$10 electronic gift card incentive the complete the survey. No personally identifiable information was collected on the main survey; however, participants must provide name and contact information on a separate form to enter for a chance to earn the incentive. Name and contact information on the incentive form was not linked back to the main surveys.

Respectively, 87 program participants and 43 service providers completed the family surveys and the home visitor surveys. Findings were published on the ORP Fusion web page.

Project ID	IRB_2022-07
Project Title	PJAC Research Supplement Study
Type of Submission	Initial Review
Type of Review	Expedited under Title 45 CFR 46
Agency Sponsor	VDSS Division of Child Support Enforcement
Funding (if applicable)	U.S. Office of Child Support Enforcement
Principal Investigator(s)	Melanie Skemer, MA
PI Affiliation	MDRC
Approved	2/8/2022
Modification	None
Approval Ends	9/30/2023
Status	In progress

Description: The PJAC demonstration tests the efficacy of incorporating procedural justice principles into child support practices as an alternative to contempt. MDRC is studying the effects of the PJAC intervention, as well as its implementation and costs ("core study"). This application outlines plans for an additional research supplement that builds on the core study. Using agency records (obtained through a name match performed by VDSS) from the state's CSE administrative system and project data already collected, the supplement will assess differences 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 goes beyond the 1,905 parents who were enrolled in the core study; it examines agency interactions with and services provided to custodial and non-custodial parents associated with approximately 300,000 child support cases in the state of Virginia between January 2019 and December 2021. The only identifier is case ID; no other personally identifiable information 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 include parents, staff, and partners who took part in interviews during the core study, as well as up to 20 staff/partners and 15 parents who consent to take part in interviews for the supplemental project. Research protocols for interviews and a copy of the data sharing agreement will be sent in a future modification.

Project ID	IRB_2022-11
Project Title	A Randomized Trial of the Effects of SNAP Work Requirement Waivers on Program Participation, Labor Supply, and Well-being
Type of Submission	Initial Review
Type of Review	Expedited under Title 45 CFR 46
Agency Sponsor	VDSS Office of Research and Planning
Funding (if applicable)	Abdul Latif Jameel Poverty Action Lab (JPAL)/MIT
Principal Investigator(s)	Heeju Jang-Paulsen, PhD; Adam Leive, PhD (University of Virginia); Tim Layton, PhD (Harvard University)
PI Affiliation	VDSS Office of Research and Planning.
Approved	6/22/2022
Modification	None
Approval Ends	6/21/2023
Status	In progress

Description: SNAP clients who are able-bodied and without dependents (ABAWDS) are required to engage in employment or other work-related activities to remain eligible for SNAP benefits. Each year, the state receives an allocation of monthly work requirement exemptions to allocate to clients at its discretion. The number of exemptions is far less than needed to remove work requirements for all SNAP beneficiaries. The purpose of this study is to assess how these exemptions impact program participation, labor force participation (future employment), and client well-being across different groups, so that DSS can target future exemptions according to its program goals.

Approximately 40,000 SNAP clients enrolled or re-certified in March through June 2022 will participate in the study. In Phase I, SNAP ABAWD clients who are subject to time-limited benefits (unless they meet work requirements) will be randomly assigned to either the control group or to one of four treatment groups. In the treatment groups, work requirements will be waived for either 6 or 12 months; recertification periods will be six months or extended to 12 months. Clients will be passively enrolled in the study through random assignment (waiver of informed consent was requested). Assignment will be made in the VACMS eligibility and enrollment system.

The study will track program participation and employment status (including earnings) in the VACMS system for each group for up to 3 years. The employment/earnings data come from the Virginia Employment Commission and are linked to VaCMS data. Annually, VDSS will transfer de-identified datasets to the UVA and Harvard based research team for data analysis.

In Phase 2 (in 2023), SSRS, a partner research firm, will conduct a survey to study well-being among a subset (5,000) of study participants. The survey will be offered online, via phone, or via mail and will include a small monetary incentive. Consent language will be included in the survey introduction. If the client opens the survey link, returns the survey, or agrees to be interviewed, that signifies their agreement to participate. The survey responses will be merged with the rest of the study data by using the client's VaCMS ID.

Project ID	IRB_2022-12
Project Title	The Perceptions of Integrating Digital Literacy with TANF Work Programs to Empower Participants for Economic Self-Sufficiency
Type of Submission	Initial Review
Type of Review	Expedited under Title 45 CFR 46
Agency Sponsor	VDSS Division of Benefit Programs
Funding (if applicable)	None
Principal Investigator(s)	Debra Jones, MA, Ed.S
PI Affiliation	Regent University (Doctoral student)
Approved	4/14/2022
Modification	None
Approval Ends	4/14/2023
Status	In progress

Description: In this study, the PI will conduct a focus group interview with current and former TANF VIEW participants to gather feedback about their involvement in the employment training and education activities. The aim of the study is to determine if TANF participants have sufficient digital competencies to work in in certain employment industries and able to earn an income sufficient to provide for their families without relying on government assistance. The study sets out to explore the perceptions of integrating digital literacy training with TANF work programs.

The PI will recruit a minimum of ten (10) current or former TANF VIEW enrollees to participate in a 60-90 minute focus group interview. The interview will take place virtually, through the Zoom web-based meeting platform. Participants must have Internet access (or the ability to call in) at home or another safe and private location.

The PI will recruit subjects by posting advertisements (flyers) in local social services offices, child care facilities, and housing projects in the Hampton Roads area. Interested individuals can contact the PI by phone for more information and to enroll in the study. The phone script will include screening questions. A printed consent form will be mailed to scheduled participants in advance of the meeting. Participants must sign and return the consent form before participating in the meeting. Logistical information and the meeting link will be sent prior to the focus group. The PI will conduct a Zoom test-run and/or tutorial with participants prior to the focus group to fix any technical or training issues that may occur. Participants will receive a \$25 gift card incentive for their participation in the focus group.

The focus group meeting will be audio-recorded. Participants' names will not be mentioned during the meeting. The meeting will be transcribed, and recorded responses will be analyzed and then destroyed immediately after the study is completed. Data will be stored on a password-protected computing device.

APPENDIX D: STUDY MODIFICATIONS/CONTINUATIONS APPROVED BY EXPEDITED REVIEW, SFY 2022

Project ID	IRB_2019-20
Project Title	Virginia Infant Toddler Support Network (VA-ITSN) and Early Childhood Mental Health (ECMH)
Type of Submission	Modification Review
Type of Review	Expedited under Title 45 CFR 46
Agency Sponsor	VDSS Child Care and Early Childhood Development (now part of VDOE)
Funding (if applicable)	US Dept. of Health and Human Services (RFA # OECD-17-052) to VDOE
Principal Investigator(s)	Amy Stutt, M.Ed
PI Affiliation	Child Development Resources
Initial Approval	7/12/2019
Modification	#2 (2/25/2022)
Approval Ends	
Status	Continuing

Description: This is an expansion of activities started by the Virginia Infant Toddler Specialist Network (VA-ITSN) under previous grants. Through a coordinated system of care, the project will provide mental health services and education to families of infants and toddlers and professional training to caregivers and early childcare teachers and directors. The training will focus 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 of the project 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. The following modifications were approved:

- 1) The PI changed from Amy Bornhoft to Amy Stutt. Amy Stutt will also serve as the PI and lead on the LENA GROW study. Arlene Kasper (VDOE) will continue to serve as the main program contact.
- 2) The project name changed from VA ITSN and ITMH (Infant Toddler Mental Health) to VA ITSN and ECMH (Early Childhood Mental Health), to include training for early childhood (preschool) providers.
- 3) The ECMHC consultation model will expand its services and training to the central Virginia region, specifically to publicly-funded early childhood programs in centers, preschools, and day homes. The enrollment and services will be delivered within a 2-tier system.
- 4) The project will use additional assessment tools for the ECMHC component of the training: CSEFEL "Inventory of Practices for Promoting Children's Social Emotional Competence" (teacher self-assessment); Intake Form; Consultant Log; Teacher Enrollment Form; Teacher Pre-Consultation Survey; Child Demographic Questionnaires (English and Spanish). Other forms are still in development and will be submitted at a later date.
- 5) Due to the COVID-19 pandemic, the study will allow for an online and phone consent process in addition to in-person.
- 6) Subject (teacher) reimbursement will increase to \$200 gift card per classroom to be spent on items related to ECMHC services.
- 7) The projects will share de-identified project data with UVA so that an evaluation of ECMHC services can be conducted.

Project ID	IRB_2019-20
Project Title	Virginia Infant Toddler Support Network (VA-ITSN) and Early Childhood Mental Health (ECMH)
Type of Submission	Modification Review
Type of Review	Expedited under Title 45 CFR 46
Agency Sponsor	VDSS Child Care and Early Childhood Development (now part of VDOE)
Funding (if applicable)	US Dept. of Health and Human Services (RFA # OECD-17-052) to VDOE
Principal Investigator(s)	Amy Stutt, M.Ed
PI Affiliation	Child Development Resources
Initial Approval	7/12/2019
Modification	#3 (3/9/2022)
Approval Ends	
Status	Continuing

Description: This is an expansion of activities started by the Virginia Infant Toddler Specialist Network (VA-ITSN) under previous grants. Through a coordinated system of care, the project will provide mental health services and education to families of infants and toddlers and professional training to caregivers and early childcare teachers and directors. The training will focus 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 of the project 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. On 3/9/2022, the IRB approved the project adding seven additional data collection forms for its evaluation. Most are surveys for child care teachers, directors, and families. The protocols for the family and teacher focus groups were also sent.

Project ID	IRB_2018-06
Project Title	Procedural Justice-Informed Alternatives to Contempt (PJAC) Demonstration
Type of Submission	Continuation Review
Type of Review	Expedited under Title 45 CFR 46
Agency Sponsor	VDSS Division of Child Support Enforcement
Funding (if applicable)	Office of Child Support Enforcement (OCSD), ACF, US DHHS
Principal Investigator(s)	Melanie Skemer, MS
PI Affiliation	MDRC
Initial Approval	6/18/2018
Modification	Not applicable
Approval Ends	
Status	Continuing

Description: Funded by the U.S. Office of Child Support Enforcement, the multi-state PJAC project tests alternatives to use of contempt to deal with non-custodial parents who fall behind on child support payments. VDSS child support case workers will randomly assign non-custodial parents who are falling behind in child support payments and possibly face contempt to either the experimental group, which accepts PJAC services, or the control group, which receives routine child support services. PJAC services include a more parent-centered approach: more intensive case review, case conferencing, NCP investigation/locating, outreach, case management, right-sizing the order, referral for support (employment) services, etc. Participants, case workers, and community partners will participate in semistructured interviews and online surveys to assess the implementation of the program. A subset of noncustodial parents will complete a 12-month follow-up survey to assess the impact of the program. Informed consent will be obtained in regards to new data collection activities (MDRC asked for a waiver of informed consent for the actual enrollment into the study and access to the administrative data). Incentives were offered for completing the survey or participating in the interview. Child support staff also participated in interviews about program implementation. Through a data sharing agreement, MRDC will maintain a supplemental database (project information on contacts, outreach, referrals, participation in support services, etc.) to which select child support agency records (from APECS), employment and earnings data, and administrative court/jail data will be linked. The goal is to assess if using alternative methods to contempt increases perceptions of fairness, improves cooperation and, in turn, results in more reliable child support payments. The study was approved by MRDC's IRB through a full-board review. Minimal risk determined.

Update: Six previous modifications were made to this study, with the last one approved on 9/23/2020. The study conducted a round of remote site visits and a staff time study. Parent interviews were conducted. Processing and analysis of various qualitative and quantitative data sources continue. Several briefs were published. As of 9/30/2020, data collection was completed and the project team is doing the analysis. The Virginia pilot enrolled 1,905 subjects. The project added new staff. Kyla Wasserman is now the study coordinator. The PI reported no adverse events/unanticipated problems or subjects lost to follow-up.

APPENDIX E: STUDIES APPROVED BY EXEMPT PROCEDURES, SFY 2022

Project ID	IRB_2022-03
Project Title	Assisted Living Facility Infection Control Survey
Type of Submission	Initial Request for Exemption
Type of Review	Exempt under 45 CFR 46.104(d)(2) & 46.104(d)(5)
Agency Sponsor	VDSS Division of Licensing Programs
Funding (if applicable)	U.S. Centers for Disease Control and Prevention
Principal Investigator(s)	Leigh Burke
PI Affiliation	VDSS Division of Licensing Programs
Approved	1/3/2022
Modification	None
Approval Ends	Not applicable
Status	Ongoing

Description: The VDSS Division of Licensing Programs is a sub-recipient of a CDC-funded Virginia Department of Health grant (Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases). In partnership with VDH, VDSS is providing essential and necessary infection prevention and control training and support to VDSS-licensed assisted living facilities and adult day care centers in Virginia. Assisted living facilities are a priority target for COVID-19 mitigation. The aim is to bolster infection prevention and control expertise and staffing, improve education and training at facilities, and provide data systems to ensure tracking and communication of infectious disease threats, thus supporting surveillance, investigation, and data analytics.

VDSS will hire staff with expertise in infection prevention and control to serve as consultants and provide training. This will help facilities increase their level of preparedness and build capacity for infection prevention against emerging disease threats such as COVID-19. Response to COVID-19 and preparedness for COVID-19 and other emerging diseases is the primary focus of this funding. On-site assessments as well as surveys will be conducted throughout the grant. All survey data collected will remain confidential and anonymous. No personally identifiable information is being collected on the survey. Participants can request additional training by providing their name and contact information in a separate online form. Names and contact information will not be linked back to survey responses.

Project ID	IRB_2022-08
Project Title	Kinship, Foster and Adoptive Families Survey
Type of Submission	Initial Request for Exemption
Type of Review	Exempt under 45 CFR 46.104(d)(2) & 46.104(d)(5)
Agency Sponsor	VDSS Division of Family Services
Funding (if applicable)	None
Principal Investigator(s)	Garrett Jones, LCSW; Julia Rubarth, LMFT
PI Affiliation	VDSS Division of Family Services (Foster Care and Adoption)
Approved	1/28/2022
Modification	None
Approval Ends	Not applicable
Status	Continuing

Description: Through the local departments of social services, the Division of Family Services (DFS) will invite kinship, foster and adoptive caregivers in Virginia to participate in a survey asking about recent (last 12 months) experiences with Family Services staff, licensed child placing agencies, and family courts. The survey is web-based, designed in Qualtrics. The LDSS and LCPAs will email the survey link to the target families. Only one survey per family is requested.

Participation in the survey is voluntary and the DFS will not have access to the identity of families who respond. No personally identifiable information will be collected. Data collection will occur during February 2022. DFS will send a broadcast about the survey, including the link, to all LDSS Family Services staff. Regional Resource Family consultants will address any questions from staff and survey participants.

DFS will use the survey results to better understand the demographic characteristics of families and children in care and assess the need for in-service training. DFS will include the findings in Virginia's Annual Report on the Five Year State Plan for Child and Family Services, which is submitted to the U.S. Department of Health and Human Services. The study is being conducted to assess delivery of services, not for research purposes.

Project ID	IRB_2022-09
Project Title	Child and Family Services Review Systemic Factors Survey
Type of Submission	Initial Request for Exemption
Type of Review	Exempt under 45 CFR 46.104(d)(2) & 46.104(d)(5)
Agency Sponsor	VDSS Division of Family Services
Funding (if applicable)	None
Principal Investigator(s)	Garrett Jones, LCSW; Deborah Eves
PI Affiliation	VDSS Division of Family Services
Approved	2/15/2022
Modification	None
Approval Ends	Not applicable
Status	Continuing

Description: The federal Children's Bureau conducts the Child and Family Services Reviews (CFSR), which are periodic reviews of state child welfare systems. The Bureau's three objectives are to: 1) Ensure conformity with federal child welfare requirements; 2) Determine what is actually happening to children and families as they are engaged in child welfare services; and 3) Assist states in helping children and families achieve positive outcomes. Ultimately, the goal is to improve child welfare services and achieve safety, permanency, and well-being for children and families in Virginia.

The Division of Family Services sent a stakeholder survey to Family Services staff in local departments of social services to gather feedback about the following processes (or systemic factors):

- (1) the child welfare information system;
- (2) the case review system;
- (3) the quality assurance system;
- (4) staff and provider training;
- (5) the service array and resource development;
- (6) the agency's responsiveness to the community; and
- (7) foster and adoptive parent licensing, recruitment and retention.

No personally identifiable information was gathered. The survey is part of a statewide assessment and DFS will use results to help inform their planning for the next round of the CFSR case reviews. The findings will be included in the Annual Progress and Services Report for the Child and Family Services Plan.

Project ID	IRB_2022-10
Project Title	Building a Stronger Child Care System in Virginia: Evaluating the subsidy system in Virginia using administrative data about child care providers
Type of Submission	Initial Request for Exemption
Type of Review	Exempt under 45 CFR 46.104(d)(4)
Agency Sponsor	VDSS Division of Family Services
Funding (if applicable)	None
Principal Investigator(s)	Daphna Bassok, PhD
PI Affiliation	University of Virginia
Approved	2/15/2022
Modification	None
Approval Ends	Not applicable
Status	Continuing

Description: Through a long-standing partnership, UVA and VDOE will assess access to early child care (ECE) throughout the Commonwealth, and evaluate how policies have influenced child care access and enrollment. Another aim of the project is to evaluate how COVID-19 has had an impact on access and enrollment. The project team will analyze site-level administrative data on child care providers, from 2016 to the present, specifically, address of child care site, provider type, approved capacity, average rates, maximum reimbursable rate, and count of children receiving subsidized child care, The data, which is routinely collected by the VDSS Licensing and Child Care Subsidy Programs, are publicly available. No individually identifiable information on children receiving care will be used. The UVA IRB deemed this study as exempt from review.

At a later date, the project may collect data from child care providers and families of children in care. For now, the project is not considered research and thus exempt from review.