ANNUAL REPORT ON HUMAN RESEARCH
State Fiscal Year 2018

October 2018

A Report of the
Department of Social Services
Commonwealth of Virginia

To the Governor and
General Assembly of Virginia

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Executive Summary

Report Mandate

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

Background

The VDSS human research committee, known as the Institutional Review Board (IRB), ensures research will be conducted in compliance with federal (45 CFR 46 et seq.) and state (§32.1-162 and 22VAC40-890 et seq.) statutes. The IRB reviews, approves, and monitors research conducted or authorized by VDSS, local departments of social services, VDSS contractors, and VDSS-licensed facilities as well as any studies that utilize or seek to gather information about VDSS and/or LDSS clients and/or employees.

The VDSS IRB reviews social or behavioral studies or evaluations of client services or benefit programs. Potential harm associated with these types of studies is categorized as minimal risk. Primarily, the IRB deals with issues of privacy, confidentiality, equitable treatment, client informed consent and, to a lesser extent, the potential of psychological harm associated with sensitive questions on surveys. To meet the responsibilities of federal and state statutes defined above, the VDSS is guided by practices provided by the Office of Human Research Protections, in the U.S. Department of Health and Human Services (USDHHS) at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/index.html.

Activities of the VDSS IRB in SFY 2018

The IRB convened twice during the fiscal year. At the first meeting, the IRB conducted a full board review and approved "The National Survey of Child and Adolescent Well-Being, Third Cohort (NSCAW-III)" study (IRB #2018-04). The IRB met again later in the year to discuss and clarify VDSS IRB policies on review of research involving children under 18 years of age and research for program improvement. The Board also discussed the new CITI training program, revisions to the IRB website and submission forms, and upcoming final revisions to the Common Rule from the USDHHS. The new IRB chair, as of March 2018, introduced herself. Four members, who have terms ending June 30, 2018, affirmed their interest in continuing to serve another three-year term. Another member, who was absent from the last meeting, recommended a replacement who attended the meeting as a guest.

The VDSS IRB adopted an enhanced training program in December 2017 through the Collaborative Institutional Training Initiative (CITI) Program for Research Ethics and Compliance Training (https://about.citiprogram.org/en/homepage/). This program is comprised of multiple modules and courses related to social-behavioral research and about human research protections. Through CITI, IRB members, researchers, and VDSS and LDSS staff who are involved in human research access this on-line training program with the anticipated goal of improving their understanding of the nuances of human research and compliance with human research protections.

During SFY 2018, seventeen (17) research studies came before the IRB. The IRB's actions are summarized below.

- The IRB determined six studies to be Exempt from Review. Federal (45 CFR 46 et seq.) and state (§32.1-162 and 22VAC40-890 et seq.) statutes describe several categories of research that do not require IRB review. However, the IRB determines if a research study meets the requirements for Exempt status. Studies submitted to the VDSS most often fall into two categories of exemption as defined in the statutes. The first category describes research using information about human subjects that is never linked (directly or indirectly) to any individual through personal identifiers. Furthermore, disclosure of the subject's information outside the research would not reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation. The second category describes research and demonstration projects that are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine public benefit or service programs.
- The IRB approved five studies by Expedited Review. A study qualifies for expedited review if research activities (1) present no more than minimal risk to human subjects, and (2) involve only secondary analysis of existing data, documents, or records originally collected for non-research purposes. The VDSS IRB Chair and one other IRB member conduct expedited reviews.
- The IRB approved one study by Full Board review, with all IRB members asked to participate. A quorum of members must be present in order to convene the meeting. Members review, discuss and vote on the study in question. The IRB's decision to approve (or not approve) the study is based on a simple majority vote.
- The IRB approved one study by Reliance Agreement. A reliance agreement is a contract between IRBs from different institutions involved in the same human research study, whereby one institution agrees to cede IRB oversight and monitoring to the other IRB. This provides a reasonable method of joint or cooperative review that reduces duplication of effort and improves efficiency.
- The IRB approved four study modifications, following approval of the initial research study submission.
- One study submitted a final report in SFY 2018, Child Care Providers and Social Emotional Development Training: Project SEED (IRB #2017-02). In compliance with the legislative mandate, results of all completed IRB-approved research studies are presented on the VDSS IRB web site (http://www.dss.virginia.gov/about/irb.cgi), under the heading "Results of Approved Projects."

Conclusion

All research approved by the IRB in SFY 2018 satisfied the regulatory definition of minimal risk and involved activities such as surveys, interviews, professional development training, job training interventions, or use of administrative data. In SFY 2019, several studies will close out and final reports posted on the IRB Internet site. At the request of the IRB Chair, the VDSS Commissioner will make one to two new appointments to the IRB, with the goal of replacing members whose terms are expiring and who do not wish to remain active on the Board. The IRB

will strive to maintain a minimum of ten members on the Board for the next three-year term. Top priorities for SFY 2019 include:

- Promoting use of the new CITI training program among VDSS and LDSS staff who are involved in departmental research;
- Helping current and new IRB members fulfill their training requirements through CITI;
- Updating IRB policies and procedures to be in compliance with the revised Common Rule that becomes effective January 1, 2019;
- Streamlining procedures and forms;
- Increasing the awareness of protecting human subjects across the Commonwealth; and
- Updating the VDSS IRB website.

SFY 2018 Annual Report on Human Research
VDSS Institutional Review Board
October 2018

Report Mandate

Section 63.2-218 of the Code of Virginia requires the Virginia Department of Social Services (VDSS) human research committee to submit to the Governor, the General Assembly, and the Commissioner at least annually a report on the human research projects reviewed and approved by the committee. The Code also requires the human research committee to report any significant deviations from the proposals as approved. This report documents State Fiscal Year (SFY) 2018 activities of the VDSS human research committee, known as the Institutional Review Board (IRB).

Background

The VDSS IRB is responsible for providing guidance and oversight to the human research protection program and for helping to maintain compliance with applicable laws, regulations, and policies. Specifically, the IRB ensures research will be conducted in compliance with federal (45 CFR 46 et seq.) and state (§32.1-162 and 22VAC40-890 et seq.) statutes. The VDSS IRB has the responsibility of protecting human subjects in studies that utilize or seek to gather information about VDSS clients and/or employees as well as local department of social services (LDSS) clients and/or employees. Human research activities reviewed by the IRB may be, but are not limited to, studies that are proposed, conducted and/or authorized by VDSS, the LDSS, VDSS/LDSS contractors, or VDSS-licensed facilities.

The IRB reviews research prior to implementation to ensure that the proposed research, first, protects the rights of clients and, second, maintains the privacy and confidentiality of information or data collected from participants. Using established regulatory criteria, the IRB may determine that a study: 1) satisfies criteria for being exempt from review, 2) is appropriate for expedited review, or 3) requires full board review. Generally, the IRB chair and/or one or two other IRB members conduct exemption determinations and expedited reviews. For a full board review, the IRB is convened and the research is reviewed and must be approved by a majority of members present at a meeting composed of a quorum.

Research submitted to the IRB involves social or behavioral studies. Many of these studies entail evaluation of delivery of programs services and/or benefits to agency clients. Risk of physical harm is unlikely for these types of studies or evaluations. Most reviewed studies qualify as minimal risk. The potential harm associated with a minimal risk study focuses on issues of privacy, confidentiality, equable treatment, client informed consent and, to a lesser extent the potential of psychological harm associated with sensitive survey questions.

Since 2006, VDSS has committed to the U.S. Department of Health & Human Services (USDHHS) that it will comply with requirements set forth in the Protection of Human Subjects regulations at 45 CFR 46 et seq. Compliance, known as a "Federalwide Assurance," is a necessary condition for VDSS to receive federal grants that include human research activities. Among other things, the terms of the assurance requires VDSS to operate an IRB. The current VDSS Federalwide Assurance (#FWA00010976) is effective through July 22, 2020 and is

renewable at the end of the term. The IRB is also registered (# IORG0004422) with USDHHS. The IRB's registration expires March 11, 2019 and is renewable at the end of the term.

The VDSS Office of Research and Planning (ORP) is responsible for administering the IRB and ensuring compliance with federal and state regulations regarding human subject research. Dr. Jeff Price, VDSS ORP Director, serves as the IRB Ombudsman. During SFY2018, Dr. Gail Jennings served as interim IRB chair and administrator from June 2017 through February 2018. Dr. Jennings has extensive IRB experience, including participating as a member since 2003 at two IRBs (Virginia Department and VDSS) as well as serving as IRB Chair and Administrator for VDSS from 2012 to 2015. In March 2018, VDSS Commissioner S. Duke Storen appointed Dr. Eleanor Brown as IRB Chair and Administrator. Dr. Brown has many years of IRB experience, including serving as IRB chair for a non-profit child welfare agency, employment as research faculty and instructor for two Universities and training students on how to submit studies for IRB review, and more than 30 years of social services research experience. The IRB is composed of ten voting members described in Appendix B. Each member is appointed by the VDSS Commissioner and serves a three-year term. IRB membership complies with state and federal human research regulations.

IRB Functions

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

The IRB is responsible for the following oversight functions:

1. Determine what activities constitute human participant research.
2. Review and determine if all research activities comply with this policy prior to the commencement of the research. In cases of approval with conditions, require investigators to make modifications to the study prior carrying out any research activities.
3. Require that information given to participants as part of informed consent is in accordance with appropriate laws and regulations. The IRB may require that additional information be given to the participants when, in the IRB's judgment, the information would meaningfully add to the protection of the rights and welfare of participants.
4. Require documentation of informed consent or waive documentation in accordance with federal and Commonwealth of Virginia laws and regulations.
5. Notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
6. Unless the study has been classified as "Exempt", conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and execute its authority to observe or have a third party observe the consent process and the research.

7. Suspend or terminate approval of research not conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and will be reported promptly to the investigator and appropriate institutional official.
8. Obtain reports summarizing the findings of completed studies and publish summaries on the VDSS Public Website.

Fiscal Year 2018 IRB Activities

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Appendix A: State Fiscal Year 2018 Study Details

Studies Approved by Exempt Review:

Project Name	Measurement of racial and other disparities in the child welfare caseload of the Charlottesville Department of Social Services.
Project_ID	2018-01
Exempt Reason	45 CFR 46.101(b)(4)
Agency Sponsor	Charlottesville Department of Social Services
Principal Investigator (PI)	Michele Claibourn, PhD
PI Affiliation	University of Virginia
Date Submitted	21-Jul-17
Date Approved	23-Oct-17
Description	The purpose of the study is to determine if there are differential responses to families involved in child welfare cases and disparities in child and family outcomes based on race, ethnicity and other demographic factors. Findings will be shared with the Charlottesville DSS and used to inform the development of local agency activities and policies (e.g., staff development, case reporting and management, community engagement) to correct for any disparities.
Status	Near completion

Project Name	Study of VDSS-DFS Training Model
Project_ID	2018-03
Exempt Reason	45 CFR 46.101(b)(5)
Agency Sponsor	VDSS Division of Family Services
Contract Num	FAM-17-058
Principal Investigator (PI)	Charmaine Brittain, MSW, PhD
PI Affiliation	University of Denver, Butler Institute
Date Submitted	19-Sep-17
Date Approved	3-Oct-17
Description	The intent of this study is to gather feedback from state and local family services workers in regards to participation in VDSS-sponsored job training and workforce development opportunities. Child welfare and adult services workers will be asked to complete a web-based survey regarding the availability, relevance and effectiveness of job training (a link to the survey will be embedded in an email sent to all staff). In addition, the Butler Institute will conduct focus group interviews ("listening groups") with VDSS management, representatives from DARS, and a sample of administrators (e.g., directors) from the local social services agencies. Findings will be used to identify gaps and problem areas in

	workforce development for both state and local social services agency staff and to develop recommendations for improvements
Status	Near completion

Project Name	Facilitated Care Reporting Pilot Project (Kinship Diversion)
Project_ID	2018-05
Exempt Reason	45 CFR 46.101(b)(4)
Agency Sponsor	VDSS Division of Family Services
Contract Num	FAM-17-082
Study Funder	Annie E. Casey Foundation
Principal Investigator (PI)	Karin Malm, MS
PI Affliation	Child Trends, Inc.
Date Submitted	06-Oct-17
Final Decision Date	10-Oct-17
Description	VDSS Family Services is entering into a data sharing agreement with Child Trends to share client administrative data on children who were diverted from entering foster care through placements with kin (other family members). The purpose of this study is to examine patterns of "diversion practice" among the local social services agencies in Virginia and to provide recommendations. Although case and client data will be sent to Child Trends for data analysis, no PII (e.g., client names, address, DOB) will be released. Original case and client IDs will be scrambled or hashed by VDSS before being released to Child Trends. Although this is part of a multi-state study, Virginia's participation is restricted to only sharing existing administrative data; no new data (key informant surveys, focus group interviews) will be collected in Virginia as has already occurred in other states. The study period is June 5, 2017 through March 31, 2019.
Status	In progress

Project Name	Normalcy Evaluation
Project_ID	2018-11
Exempt Reason	45 CFR 46.101(b)(4)
Agency Sponsor	VDSS Division of Family Services
Principal Investigator (PI)	Em Parente, PhD, MSW, LCSW
PI Affiliation	Virginia Department of Social Services
Date Submitted	26-Feb-18
Date Approved	14-Mar-18
Description	The purpose of this evaluation is to determine the degree of comfort and/or concern of local department of social services

	(LDSS) foster care caseworkers, licensed child placement agency (LCPA) workers, congregate care workers, and foster parents as they develop or implement a normalcy frame of reference in working with children and youth in the custody of the LDSS. This evaluation will help to guide in the development of additional guidance, support, and training surrounding normalcy in foster care in Virginia. The Virginia Department of Social Services (VDSS) Division of Family Services (DFS) has organized a steering committee to aid in the implementation of normalcy. The steering committee consists of representatives from VDSS, LDSS's, and stakeholders, and has the assistance of the Capacity Building Center for States. The steering committee assisted with the development of the normalcy evaluation survey.
Status	In progress

Project Name	VDSS ROLS Survey
Project_ID	2018-13
Exempt Reason	45 CFR 46.101(b)(5)
Agency Sponsor	VDSS Regional Operations and Local Support (ROLS)
Principal Investigator	Angela Morse
PI Affiliation	VDSS Regional Operations and Local Support (ROLS)
Date Submitted	26-Apr-18
Date Approved	27-Apr-18
Description	At the request and authorization of the Virginia Department of Social Services (VDSS) Chief Deputy Commissioner, the VDSS Regional Operations and Local Support (ROLS) Division is conducting an organizational assessment of selected local County Departments of Social Services (LDSS). The purpose of the project is to improve delivery of public benefits and services. As part of the assessment ROLS will implement a voluntary survey – the LDSS Organizational Assessment Survey -- that may be conducted online or in-person. Data collected from the survey will not include any identifying information other than LDSS name, with an option for the employee to identify his or her section, i.e. Benefits, Services, or Administration/other. Aggregated survey results will be shared only with the LDSS Board and VDSS leadership and with VDSS employees as needed for program improvement. The ROLS Senior Organizational Effectiveness Consultant, who has extensive experience in data analysis, organizational assessment, process documentation, and incorporating user/client stories, will lead the project.
Status	Ongoing

Project Name	DFS Input for CFSR PIP
Project_ID	2018-14
Exempt Reason	45 CFR 46.101(b)(5)
Agency Sponsor	VDSS Division of Family Services
Principal Investigator	Carl Ayers, MSW
PI Affiliation	VDSS Division of Family Services
Date Submitted	5-May-18
Date Approved	15-May-18
Description	In conjunction with the federal Children's Bureau and consultants from their Quality Improvement Center (US DHHS, ACF), VDSS Division of Family Services seeks to conduct focus groups and surveys of local DSS employees. The purpose is to inform the Divisions CFSR Program Improvement Plan (PIP) to the Bureau.
Status	Near completion

Studies Approved by Expedited Review:

Project Name	The LIFE (Longitudinal Infant and Family Environment) Study
Project_ID	2018-02
Agency Sponsor	VDSS Division of Family Services
Contract Num	FAM-17-084
Principal Investigator	Sunny H. Shin, PhD
PI Affiliation	Virginia Commonwealth University
Date Submitted	01-Sep-17
Date Approved	19-Sep-17
Description	This study examines whether or not enhanced patient education about sudden infant death syndrome (SIDS)/sudden unexpected infant death (SUID) and safe sleep environment as well as use of a baby box decreases unsafe sleep practices at home. A total of 1,100 women who give birth at Children's Hospital of Richmond will be recruited for this study. Hospital personnel (e.g., nurses, residents/interns, medical students) will conduct discharge education with patients and be involved in recruiting potential participants for the study. Patients will be randomly assigned to either the experimental (study) group or the control group (550 in each group).
Status	In progress

Project Name	Procedural Justice-Informed Alternatives to Contempt (PJAC) Demonstration
Project_ID	2018-06
Agency Sponsor	VDSS Division of Child Support Enforcement
Study Funder	Office of Child Support Enforcement (OCSD), ACF, US DHHS
Principal Investigator (PI)	Cindy Redcross, MS
PI Affiliation	MRDC
Date Submitted	11-Oct-17
Date Approved	18-Jun-18
Description	The Virginia Division of Child Support Enforcement is one of several states whose clients will be participating in this demonstration project. The project is federally funded (through the Office of Child Support Enforcement). The Georgia Division of Child Support Services (GA DCSS) is the lead funded agency, and MRDC is the evaluator for this project. In this demonstration project, non-custodial parents who are likely to be brought in contempt for non-failure to pay child support will be randomly assigned to either an intervention group, who receives alternative services, or a control group, who will follow normal practices for contempt cases. Of the 2300 parents participating in Virginia, 65% will be assigned to the intervention group, 35% will be assigned to the control group.
Status	In progress

Project Name	An Exploratory Geoanalysis of Child Maltreatment, Related Fatality, and the Pathophysiology Associated with Chronic Exposure to Adverse Events in the Commonwealth of Virginia
Project_ID	2016-09
Agency Sponsor	VDSS Division of Family Servcies
Principal Investigator (PI)	Carl Ayers, MSW
PI Affiliation	VDSS Division of Family Servcies
Co-PI	Dyann Daley, MD
Co-PI Affiliation	Predict Align Prevention, Inc.
Date Submitted	03-Jan-18
Date Approved	2-Feb-18
Description	The proposed study will retrospectively investigate the rate and nature of child maltreatment occurrence and distribution in select localities within the Commonwealth of Virginia. VDSS research staff will use data from state fiscal years 2014-2017 for Richmond City. In order to track outcomes longitudinally and to evaluate the effectiveness of prevention strategies that are implemented locally, VDSS will conduct follow-up analysis, that is, periodically (every six months) re-run the spatial analysis using additional data collected for state fiscal

	years 2018 through 2021. Richmond City will be the analysis area for a pilot project. If successfully implemented, the same approach will be replicated in other localities throughout the state. Using geospatial analytical techniques (e.g., kernel density mapping, risk terrain modeling), research staff at VDSS will explore the geospatial patterns of associated risk and protective factors, if such are found to exist. Investigators will generate a series of hotspot, coldspot, and risk terrain maps that will be applied to community and neighborhood centered alignment and prevention efforts. Risk factors include, but are not limited to, geographic locations of crimes, socioeconomic indicators, commercial properties and zoning, and environmental characteristics. This study will also include a cross-sectional analysis of community-based assets to determine if such assets assert a protective influence on children and families and to locate those geographic areas within the state that are lacking in services and protective factors that may be influential in preventing child maltreatment.
Modification Date	30-Apr-18
Modification	Added one individual to Co-PI's research team
Status	In progress

Project Name	Black Female Adolescents' Perspectives Regarding Their Sexual and Reproductive Health (SRH) Needs While in Foster Care
Project_ID	2018-10
Agency Sponsor	NA
Principal Investigator (PI)	Christina Ross, BSN, Doctoral Candidate
Organization	University of Virginia School of Nursing
Date Submitted	19-Feb-18
Date Approved	14-May-18
Description	A qualitative descriptive study will be conducted to explore and describe perceptions of female African American adolescents about their SRH. The purpose of this study is to better understand the multiple factors that contribute to their SRH disparities from their perspectives. This study will specifically aim to: 1) Identify their perceived SRH needs; 2) Describe their perceived risks and strengths that may influence their SRH; and 3) Explore contextual factors, including communication with foster caregivers, that relate to decision making and choices re: sexual behavior.
Status	In progress

Project Name	Vision 21: Linking Systems of Care (LSC) Listening Tour

Project_ID	2018-12
Agency Sponsor	US Department of Justice, Office for Victims of Crime
Principal Investigator (PI)	Anna Cody, MS
PI Affiliation	VDSS Office of Community & Volunteer Services (CVS)
Date Submitted	11-Apr-18
Date Approved	24-May-18
Study Funder	US Department of Justice, Office for Victims of Crime
Description	The Vision 21 Linking Systems of Care (V21 LSC) Listening Tour will provide children/youth, families and direct service providers an opportunity to share information about how they experience coordination and provision of services in the commonwealth. The listening tour will address goal 2 (enhance stakeholder involvement in service planning/delivery) and 3 (link systems of care by improving service coordination across child-serving systems) of the V21: LSC Virginia Demonstration project. The tour will include at least five localities, where listening sessions of approximately 2 hours may be held with each stakeholder group separately. Sample question guides have been developed and reviewed for each participant group. These guides may be adjusted by V21 staff for relevancy as the listening tour progresses. Questions for children/youth and family groups will focus on experiences with accessing and receiving services. Questions for service providers will focus on experiences of providing services for children/youth and families.
Status	In progress

Studies Approved by Full Board Review:

Project Name	The National Survey of Child and Adolescent Well-Being, Third Cohort (NSCAW-III)
Project_ID	2018-04
Agency Sponsor	VDSS Division of Family Services
Study Funder	USDHHS, Administration for Children and Families
Principal Investigator (PI)	Melissa Dolan, PhD
PI Affiliation	RTI International
Date Submitted	29-Sep-17
Final Decision Date	14-Nov-17
Description	The National Survey of Child and Adolescent Well-Being (NSCAW) is a nationally representative, longitudinal survey of children and families who have been the subjects of child protective services (CPS) investigations. With funding and support from the U.S. Children's Bureau and the Office of Planning, Research and Evaluation (OPRE), NSCAW examines

	child and family well-being outcomes in detail and seeks to relate those outcomes to families' experiences with the child welfare system (e.g., service utilization) and to family characteristics, community environment, and other factors. Starting in 1997, interviews and assessments were conducted with two cohorts of children (and their primary caregivers) who were served by local child welfare agencies randomly selected across the country. For each child, the assigned caseworker was also interviewed. For the third cohort (NSCAW – III), baseline interview data will be collected in 2017-2019; 18-month follow-up interviews will be carried out in 2019-2021. After having participated in the first two cohorts, Virginia is again participating in the third cohort of this survey.
Status	In progress

Studies Approved by Authorization Agreement:

Project Name	Quality Improvement Center for Workforce Development Study
Project_ID	2018-07
Agency Sponsor	VDSS Division of Family Services, NGA Three-Branch Award
Study Funder	USDHHS, ACF, Children's Bureau
Principal Investigator (PI)	Anita P. Barbee, PhD
PI Affiliation	University of Louisville
Date Submitted	3-Nov-17
Date Approved	1-Dec-17
Authorization Agreement	As provided for in OHRP regulations, VDSS enterered into an Authorization Agreement (signed on 11/2/2017) with the University of Louisville. VDSS will rely on the University of Louisville's IRB to review the study. Copies of the signed MOU and Data Sharing Agreement were received on 2/9/2018
Description	The U. S. Department for Health and Human Services (DHHS), Administration on Children and Families (ACF), Children's Bureau funded a Quality Improvement Center on Workforce Development (QIC-WD) for $15 million across five years. The Center is located at four partnering universities including the lead university and lead for workforce interventions- the University of Nebraska at Lincoln- the lead for evaluation and research- the University of Louisville- the lead for implementation - the University of Colorado-Denver and the lead for organizational culture and climate- the University of Tennessee. The QIC-WD will partner with public child welfare agencies to conduct a multi-site demonstration project, with the overall goal of implementing a workforce development

	framework and evidence-based and evidence-informed interventions to improve workforce and child and family outcomes for state and tribal systems. The implementation of these workforce interventions will be rigorously evaluated, establishing evidence that will add to the child welfare knowledge base.
Status	In progress

Study Modifications Approved:

Project Name	Wendy's Wonderful Kids Post-Adoption Study: How are adopted foster youth faring as young adults
Project_ID	2014-04M
Agency Sponsor	VDSS Division of Family Services
Principal Investigator (PI)	Karin Malm
PI Affiliation	Child Trends
Date Submitted	17-Jan-14
Date Approved	26-Mar-14
Description	Child Trends, with funding from the Dave Thomas Foundation for Adoption (DTFA), is undertaking a national study to assess the well-being of the older children adopted through the Wendy's Wonderful Kids (WWK) adoption recruitment program.
Continuation	The PI submitted a continuation and modification on September 8, 2017. The study is expected to end recruitment in December 2018.
Continuation Approved	8-Sep-17
Modification	Current recruitment materials state that we will interview young adults once they turn 19. Over 20 young people who turn 19 between June-December 2018 have already agreed to share their contact information with the research team. Modification proposes making a minor change to the recruitment procedures, to clarify that young people can be interviewed earlier, at age 18. Planning to end recruitment in December 2018, reaching out to young people earlier will give us more time for recruitement and a better chance at reaching them. Also hope that interviewing young people earlier will help avoid non-response due to potentially outdated contact information. Updated all recruitment materials that mention the age that the young person will be interviewed. Also, have received approval for this modification from the Child Trends IRB and have attached the modification approval letter.
Modification Approved	8-Sep-17
Status	In progress

Project Name	Assessing the Barriers that Constrain the Adequacy of SNAP Allotments (SNAP Barriers Study); Short Name: The Food and Your Household Study
Project_ID	2016-03
Agency Sponsor	VDSS Benefit Programs, SNAP
Study Funder	US Department of Agriculture, Food and Nutrition Services
Principal Investigator (PI)	Maeve Gearing, PhD
PI Affiliation	Westat
Date Submitted	14-Sep-15
Date Approved	24-Apr-17
Description	On behalf of the Food and Nutrition Service (FNS), United State Department of Agriculture (USDA), Westat will conduct a study among Supplement Nutrition Assistance Program (SNAP) participants to identify the major individual, household, and environmental
Modification 1	In response to OMB concerns about the effectiveness of using pre-incentive payments in combination with post-survey incentives to improve participation, the investigators will conduct an experiment. Subjects will be randomly assigned to two different incentive payments.
Modification 1 Approved	01-Feb-18
Modification 2	This second requested modification was received by VDSS IRB April 10, 2018. The request was to approve substituting reminder postcards for the automated telephone reminder calls after the survey is mailed. The regulations (45 CFR 46) permit expedited review of minor changes in previously approved activities.
Modification 2 Approved	23-Apr-18
Status	In progress

Project Name	Vision 21: Linking Systems of Care (LSC) Listening Tour
Project_ID	2018-12
Agency Sponsor	US Department of Justice, Office for Victims of Crime
Principal Investigator (PI)	Anna Cody, MS
PI Affiliation	VDSS Office of Community & Volunteer Services (CVS)
Date Submitted	11-Apr-18
Date Approved	24-May-18
Study Funder	US Department of Justice, Office for Victims of Crime
Description	The Vision 21 Linking Systems of Care (V21 LSC) Listening Tour will provide children/youth, families and direct service providers an opportunity to share information about how they experience coordination and provision of services in the commonwealth. The listening tour will address goal 2 (enhance

	stakeholder involvement in service planning/delivery) and 3 (link systems of care by improving service coordination across child-serving systems) of the V21: LSC Virginia Demonstration project. The tour will include at least five localities, where listening sessions of approximately 2 hours may be held with each stakeholder group separately. Sample question guides have been developed and reviewed for each participant group. These guides may be adjusted by V21 staff for relevancy as the listening tour progresses. Questions for children/youth and family groups will focus on experiences with accessing and receiving services. Questions for service providers will focus on experiences of providing services for children/youth and families. Approved modification for VDSS account tracking, VDSS PI will record receipt of participation Gift Card using participant alias, and provide a receipt to each participant. Did not approve recording participant contact information to notify of any changes
Modification	
Modification Approved	22-Jun-18
Status	In progress

Appendix B: VDSS IRB Membership for SFY 2018

VDSS Institutional Review Board Member Roster SFY2018			
Last Name	**First Name**	**Highest Educational Degree(s)**	**Institutional Affiliation (Position Title)**
Brown[1]	Eleanor	MSW, MPH, PhD Maternal and Child Health	VDSS, Office of Research and Planning (Research Associate Senior)
Cleary	Hayley	PhD, MPP**;** Developmental Psychology; Public Policy	Virginia Commonwealth University (Assistant Professor)
Disse[2]	Mary	BA; Psychology Post-Baccalaureate Certificate in Information Systems	VDSS, Division of Information Systems (Business Analyst)
Hawley	Carolyn	PhD, CRC**;** Health Related Sciences/Rehabilitation Leadership; Certified Rehabilitation Counselor,	Virginia Commonwealth University (Associate Professor)
Huff	Richard	PhD; Public Policy and Administration	Virginia Commonwealth University (Assistant Professor)
Jennings	Gail	PhD; Psychology	VDSS, Office of Research and Planning (Research Associate Senior)
Jones-Haskins[2]	Erika	MSW; Social Work	Department of Behavioral Health & Developmental Services (Community Support Services)
Owen	Myra	PhD; Health Related Sciences/Gerontology (retired summer 2017)	VDSS, Office of Research and Planning (Research Associate Senior)
Parente	Em	PhD; Social Work	VDSS, Division of Family Services (Program Manager)
Schneider	Jessica	MS; Criminal Justice	Virginia Department of Juvenile Justice
Temoney[2]	Tamara	PhD; Public Policy and Administration	Hanover County Department of Social Services (Assistant Agency Director)
Price[3]	Jeff	PhD; Economics	VDSS Office of Research and Planning (Director)
[1]IRB Chair and Administrator; [2]Nonscientific member; [3]IRB Ombudsman			

Appendix C: Minutes of IRB Meetings for SFY2018

Date: 10/27/17
Place: VDSS, 801 East Main Street Richmond, VA, 15th floor, Room # 1518
Call to order Time: 1:30 pm
Members Present: 5 members, 4 for a majority:

IRB Member Attendance Table

Present	Scientist (S) Non-scientist (N)	IRB Member	In person (I) Teleconference (TC) Telephone (TP)	Arrival Time	Departure Time (s)
☐	S	Cleary, Hayley, PhD, MPP			
☐	N	Disse, Mary, B.A.			
☐	S	Hawley, Carolyn, PhD, CRC			
☐	S	Huff, Richard, PhD			
☒	S	Jennings, Gail, PhD	I	1:25 pm	2:40 pm
☒	N	Jones-Haskins, Erika, MSW	TC	1:34 pm	2:40 pm
☒	S	Parente, Em, PhD, LCSW	TC	1:32 pm	2:40 pm
☒	S	Schneider, Jessica P.	TC	1:32 pm	2:40 pm
☐	S	Temoney, Tamara, PhD			
☒	S	Price, Jeff, PhD*	TC	1:32 pm	2:40 pm

Review of Minutes from Previous Meeting(s):

Meeting Date	Accept as is	Accept with Revisions*	Revise & Resubmit*	*see minutes for revision
N/A	☐	☐	☐	☐
Requested change to the minutes: N/A				

A. **New Protocol(s)**:

Study Title: The National Survey of Child and Adolescent Well-Being (NSCAW)			
VDSS IRB # 2018-04			Sponsor/Funder: ACF
Investigator: Melissa Dolan, PhD (RTI)			Primary reviewer(s): Gail Jennings
N/A	Yes	No	Committee Review included, but was not limited to the following areas:
☐	☒	☐	Investigator included CV?
☐	☒	☐	Investigator has no conflict of interest that would compromise the integrity of the study?
☐	☒	☐	Does the study specifically target a vulnerable population?

☐	☒	☐	Written informed consent will be obtained from the subjects?
☐	☒	☐	This study enrolls children and written informed consent will be obtained from the child's parent or guardian?
☒	☐	☐	This study may enroll adults who are not competent to provide informed consent? (Written informed consent will be obtained from subjects' legally authorized representative).
☐	☒	☐	Consent document accurately describes the important aspects of the study?
☐	☒	☐	Consent document is written in a way likely to be understood by prospective subjects?
☐	☐	☒	The following revisions to the consent document are required for final study approval:
☐	☒	☐	Prospective subjects will be recruited from: Albemarle and Sussex DSS
☐	☐	☒	A research advertisement will be used?
☒	☐	☐	The following revisions to advertisement(s) is/are required for final study approval:
☐	☒	☐	This study provides reimbursement or payment to subjects for their participation in the study?
☐	☒	☐	The level and schedule of reimbursement/payment is reasonable in relation to study procedures?
☒	☐	☐	Subjects for whom the payment is likely to be coercive will be excluded from the study?
☐	☐	☒	Is there coercion or undue influence?
☐	☒	☐	Risks and discomforts of research participation were thoroughly evaluated?
☐	☒	☐	Risks are minimized by research design?
☐	☒	☐	Main risks of research participation are adequately summarized in the consent document?
☐	☒	☐	Participation in this research will not directly benefit research participants?
☐	☒	☐	This research may benefit people in the future?
☐	☒	☐	Risks of research participation are reasonable in view of potential benefits?
☐	☒	☐	Provisions to protect the privacy of subjects are adequate?
☐	☒	☐	Provisions to protect confidentiality of data are adequate?
☐	☒	☐	Are inclusion criteria clearly stated?
☐	☒	☐	Are exclusion criteria clearly stated?
☐	☒	☐	Is there a need for ongoing data monitoring for the purpose of identifying unexpected results that would indicate a need for study revision?
Discussion and Questions:			The focus of the review was on the research activities connected with collection of the baseline data. Since RTI did not provide a plan for contacting participants and collecting more data at 18 months follow-up, RTI must submit these materials for a separate IRB review before collecting any follow-up data. The below-mentioned comments and questions are relevant only to the research activities associated with collecting baseline data. 1. The IRB members discussed state laws and regulations governing who can act as a legally authorized representative (LAR) to consent for minors in the custody of the local social services agency. If the child's parents retained their parental rights, the parents would provide consent for the child. If the parents' rights were terminated,

according to state law, the local agency and/or foster parents cannot consent on behalf of the child. The decision must be deferred to a family court judge. The local agencies have a process in place for obtaining consent from the family or juvenile court judge when minors require non-emergency care; we assume that they will follow a similar protocol for obtaining consent for minors to participate in human subjects research.

2. In the "Attachment_Data Elements_Monthly Sample File Submissions" document in the Data Sharing folder, a list of requested data elements includes the child's SSN. VDSS cannot release the child's SSN without permission from the client and/or parent (or legally authorized representative). Instead, the client ID may be used for linking the interview data to the CPS client administrative records. Furthermore, the mother's SSN will not be released unless permission from the mother is obtained.
3. In the Data Linkage consent form, the participant is asked to provide consent for obtaining and linking secondary data from other sources (e.g., CPS records, quarterly earnings and disability benefits from SSA and National Directory of New Hires) to the interview data. Furthermore, the PI mentions allowing "some researchers" to use the interview data and data from other sources ("We will allow some researchers to do studies that combine your NSCAW interview with the information we collect from other sources…"). The interview and secondary data will be stored in NDACAN's data repository at Cornell University and made accessible to other researchers outside of the organization through licensing arrangements. The participant should be provided separate prompts (check boxes) to consent to the data linkage, the sharing of data with other researchers, or both.
4. If RTI intends to release the child's linked health information to other researchers (through public use data files), explicit consent/assent should be obtained.
5. In the "Request for Approval of Research Protocol_NSCAW III" document, on page 19, the interviewer requests the caregiver respondent's SSN ("**Collecting Social Security Numbers**. At the end of the caregiver interview, caregivers will be asked for their Social Security Number (SSN). NSCAW III will collect SSNs for longitudinal tracing and locating purposes as well as data linkage authorized by the respondent."). Does the field representative obtain informed consent from the caregiver to use his SSN in this linkage? I did not see this addressed in the Data Linkage consent form. Is the child's SSN also requested at the end of his or her interview?
6. In the Request for Initial Review form, on page 11, the data files used for sampling purposes will be destroyed by May 2022. Will any other project data (e.g., consent forms, recorded verbal responses, linked data) be destroyed or live on in perpetuity through the public use data files? The PI should should describe the timeline and plan for how the project's raw electronic data – consent forms, interview data, linked data and any other data stored in your document management system (DocMan) -- will be handled after the end of the project.
7. In the "Introductory Scripts", the PI describes what the field representative says when approaching potential participants at their home.
    a. Under what circumstances would the field representative approach the respondent's home to attempt to schedule the interview (e.g., phone is out of order, phone is not picked up)? The protocol for recruiting families who are not accessible by phone needs to be clarified.
    b. If the respondent answers "No" (he or she had not received the letter), and the field representative proceeds to read the contents of the letter, is the respondent given adequate time to consider whether or not to arrange an interview? Does the field representative immediately attempt to schedule an interview time at that time, or instead does the field representative place a call to the respondent's home at a later time? RTI should not place undue pressure on the respondent to agree to schedule an interview.

	8. In the "Request for Approval of Research Protocol_NSCAW III" document, on page 10 (and again on page 13), the estimated average time of the caregiver interview is listed as 80 minutes, but elsewhere (e.g., NSCAW Brochure, Initial Review Form, Caregiver Informed Consent) it is stated as either 90 minutes or 100 minutes. Confirm the average length of time (it can be expressed as a range of minutes) for the caregiver interview and insure that it is stated consistently throughout all documents, especially the caregiver lead letters and consent forms. 9. In general, how have children ages 7-10 years dealt with the consent process and length of the interview? In regards to younger children (e.g., 7-10 years), were they able to complete the ACASI portion of the interview with few problems in using the technology? During Waves 1 and 2 combined, did RTI report any Adverse Events involving younger children experiencing distress when answering sensitive questions? Were there any adverse events involving older youth (e.g., age 11-17 years)? 10. Is there a specific protocol in place for dealing with *distressed* children? The approach and script described in the Distressed Respondent Protocol (Appendix G) appears to be targeted to adults. The language should be simplified for children. 11. In the Caregiver Consent Form and Fact Sheet, what is the "12-month period" (as in "All of the children had contact with the child welfare system during a 12-month period.") referring to? 12. In the Data Linkage consent form, the participant is asked to provide consent for linking their interview data with data from other sources, specifically, child welfare administrative data (from OASIS), earnings and disability benefits data from SSA, collected from other sources (e.g., SSA), and for allowing other researchers to use their data. Where in the consent/assent forms do you obtain permission to release the interview data to other researchers via public use data files? 13. A timeline for destruction of the interview data (including recorded responses) and other linked data needs to be clearly described. 14. The protocol for recruiting families who are not accessible by phone needs to be clarified. Did the protocol describe approaching the family in-person at their home? What accommodations are made to allow the family sufficient time to make a decision about participation and to arrange a separate time to conduct the interviews? 15. How have children ages 7-10 years generally dealt with the consent process – length of the interview, administration of parts of the interview using the Computer-Assisted Personal Interview (CAPI) method, and types of questions posed in the interview, particularly questions of a sensitive nature? Do you use other methods for asking young children (ages 7-10 years) questions on sensitive topics and recording responses? 16. Is there a specific protocol in place for dealing with distressed children? The approach and script described in the Distressed Respondent Protocol (Appendix G) appears to be targeted to adults. 17. Protocol needs to clarify if the child and caregiver interviews are administered concurrently or back-to-back. What accommodations are made for families who can't complete both interviews in the allotted time? 18. Need to confirm with the PI that this request for approval covers the period when the baseline interview data is collected. If the PI is seeking approval for follow-up interviews, the PI must submit a description of their protocol for recruitment, obtaining consent and administering the survey instrument as well as consent forms and data collection tools. 19. Questions were raised by one member regarding the timing of the child and caregiver interviews on the same day. Upon reading the protocol, it has been determined that the child and caregiver interviews are completed sequentially, not simultaneously.
Other Action Items:	The IRB Coordinator will reach out to RTI to respond to the above-mentioned items and questions. We will allow up to 10 business days (by November 16) for a response. The response will be shared with the IRB members present at the meeting via email, and these

	members will electronically vote on whether or not to approve this study. The final vote came in 11/14/2017.			
Controverted issues:				
Decision:	Approve ☒	Approve with Conditions ☐	Table ☐	Disapprove ☐
Vote	Total Voting =5	Vote: For =5	Opposed =	Abstained =
Names of Members who abstained				

Modification(s): N/A – none at this time.

Continuing Review(s): N/A – none at this time.

Tabled Study(s): N/A – none at this time

Adjourned Time: 2:40 pm

Date: June 28, 2018
Place: VDSS, 801 East Main Street Richmond, VA, 7th floor Conference Room
Call to order Time: 9:25 am
Members Present: 7 members, 4 for a majority:

IRB Member Attendance Table					
Present	Scientist?	IRB Member	In person (I) Teleconference (TC)	Arrival Time	Departure Time
☒	Y	Brown, Eleanor, PhD	I	9:00 am	11:10 am
☒	Y	Cleary, Hayley, PhD,	I	9:10 am	10:54 am
☐	N	Disse, Mary, B.A.			
☒	Y	Hawley, Carolyn, PhD,	I	9:15 am	11:10 am
☐	Y	Huff, Richard, PhD			
☒	Y	Jennings, Gail, PhD	I	9:00 am	11:10 am
☒	N	Jones-Haskins, Erika,	I	9:20 am	10:52 am
☒	Y	Parente, Em, PhD,	I	9:29 am	11:10 am
☐	Y	Schneider, Jessica P.			
☐	Y	Temoney, Tamara, PhD			
☒	Y	Price, Jeff, PhD*	I	9:20 am	10:20 am

* VDSS IRB Ombudsman and Alternate

Others present at any time during the meeting:			
Name	Time arrived	Time departed	role during the meeting
Amin, Dhara	9:10 am	11:10 am	Representing DJJ

Review of Minutes from Previous Meeting(s):				
Meeting Date	Accept as is	Accept with Revisions*	Revise & Resubmit*	*see minutes for revision
N/A	☐	☐	☐	☐
Requested change to the minutes: NA				

Old Business: None

New Business:

Future Meetings, Correspondence & Communication: The Chair proposed having the Board meet at least twice yearly. All members present agreed that this would be a good practice.

Board Membership and Term Expirations: As part of the introductions, the Chair (E. Brown) asked specific members if they were willing to renew their terms to serve on the Board. Several members agreed to renew once their terms expired. Dhara Amin, DJJ research analyst and guest at this meeting, will replace board member Jessica Schneider (DJJ). Dhara was a former paralegal. The change is subject to approval by the VDSS Commissioner. Since he has not

recently participated in IRB activities or communicated with the Chair, the Chair will contact Richard Huff to determine his current level of interest in serving as a member.

The Chair recommended that the IRB recruit new members, especially people who do not have a scientific or research background. Board members suggested reaching out to the following organizations: child advocacy groups (e.g., CASA, GAL), VCU Wilder School for Public Policy, VCU School of Social Work, Virginia Department of Education, and VCU Partnership for People with Disabilities (Parthy Dinora was specifically mentioned). Others suggested adding community stakeholders who represent or serve vulnerable populations.

CITI Training & Requirements: The Chair promoted use of CITI (Collaborative Institutional Training Initiative) for training IRB members, researchers, and VDSS program managers and staff. The Chair cited the depth and breadth of the courses and recommended it as a good resource for understanding human research protections. Aside from required courses, members are encouraged to select and complete supplemental courses based on personal interest, fit with their job, or relevance to assigned reviews. Since purchasing the agency's CITI subscription in November 2017, both the VDSS IRB Chair and G. Jennings completed all required coursework for IRB administrators. Subsequently, VDSS changed the learning plans (i.e., reduced the number of required courses) for each learner group. The Chair extended the deadline for IRB members to complete CITI training to December 31, 2018. Most members present indicated that they have previous experience using CITI for continuing education. The VDSS IRB recently purchased the "Revised Common Rule" courses (see comments below). The Chair will send further instructions to the Board on how to access the new courses.

Final Revisions to the Common Rule (Final Rule): The federal government recently revised the Common Rule regulations in regards to human subject's research protections. Among other things, this will have a major impact on administrative processes (e.g., referring multi-site studies to a single IRB, exempting certain studies or requiring a limited expedited review). The federal government extended the deadline for implementing the new Final Rule to January 21, 2019. See note above re: purchase of Revised Common Rule module from CITI.

IRB Role in Data Sharing Agreements: As Director of the Office of Research and Planning (ORP), J. Price shared his recent work in creating an internal administrative process for authorizing the release (sharing) of client-level data to outside organizations that request DSS administrative data. A data sharing agreement or MOU will be required between VDSS and the requesting organization.

Recently, VDSS began developing a CRM (customer relationship management) tool to track constituent requests. As an add-on to the system, the CRM will allow ORP users to track and report on all data requests (including those that involve client level data with or without personal identifiers) and creation of inter-agency data sharing agreements. All customer requests for DSS client-level data (with or without PII) will go to ORP. ORP will obtain approval from Business Owners prior to release of any data. As part of the workflow, if a customer requests PII client-level data, the system will trigger an email notification to the Chair that the project requires IRB review. [Requests for summary, or aggregate, data will not trigger a request for IRB review.] The CRM will undergo user acceptance testing (UAT) on July 9-20 with testing participants to

include the Chair and one other IRB member from ORP. At the earliest, the final application will launch on July 23. Both the new data sharing policy and the CRM will help VDSS move toward a "more consistent approach" in approving and releasing client level data. Furthermore, this will encourage better communication between the VDSS Divisions and the IRB in regards to research and data sharing activities and result in fewer "missed opportunities" for the Board to review studies.

Both initiatives mentioned above were prompted by instances where the Research and Planning Office and the IRB were not informed about research and data sharing activities carried out by other Divisions and by the local social services agencies.

The Chair presented examples of personal identifiers. Members agreed that administrative ID numbers assigned to clients might be considered PII.

IRB Requests for Review: G. Jennings proposed eliminating the IRB *Request for Exemption Determination* form and instead expanding the IRB *Request for Initial Review* form. The new form will capture all information necessary to making a determination that the study under review 1) involves human subjects, 2) meets the definition of being research, and 3) is eligible for IRB review (not exempt). Guest Dhara Amin added that her institution uses a form with a cover letter. Revising the IRB form may reduce the need to request more information from the PI later in the process.

Research for Program Improvement: The Chair raised the questions of what constitutes "research" and if studies conducted for the purpose of program evaluation or quality improvement should be exempt from IRB review. Members agreed that program evaluation/quality improvements studies in regards to delivery of services and benefits would be exempt from review. Members agreed that employee surveys and work climate studies qualify for IRB review and that employees are subject to the same protections as DSS clients. Several members recommended using checklists and decision trees to help determine if a project involves human subjects, if the study is research, and if the study would be exempt under any of the categories defined in the Common Rule. Members supported the Chair's position that the researcher does not have the discretion to make that determination.

The Chair asked for clarification on the meaning of certain terms used in Category 5 (45 CFR 46.101(b)(5)). Specifically, she asked if the provision "research and demonstration projects which are conducted by or subject to the approval of department of agency heads" applies to State department or agency heads, such as the DSS Commissioner. Board members agreed that the rule could be applied to studies conducted by state agencies (in this case, VDSS) or authorized by state agency heads (i.e., DSS Commissioner or Deputy Commissioner).

Research with Children When Otherwise Exempt: The Chair asked for clarification on applying certain exemption rules to studies involving children. Members agreed that only two categories apply: 1) studies involving public observations where the investigator does not interact with the child, and 2) situations where children are completing tests or assessments in an educational setting. Otherwise, all other exemption categories (e.g., being part of a program or quality improvement study) apply only to adults. Consequently, studies with child subjects will require

expedited or full board review. E. Parente and J. Price cited examples of how the IRB handled past VDSS studies involving children, specifically, children in foster care. Some members mentioned unique state and federal regulations that apply to children in foster care (e.g., participation as subjects, obtaining informed consent from legal guardians). While there is general agreement that research with human subjects under age 18 should not be given exemption from IRB review, members present at the meeting agreed that the Chair should gather more input from the full membership before making any changes to policies in regards to use of children in research.

Miscellaneous: Members approved revisions to the meeting minute's template that will allow the note taker to capture discussion about IRB processes and other administrative matters not related to studies under review.

New Protocol(s): N/A – none at this time.

Modification(s): N/A – none at this time.

Continuing Review(s): N/A – none at this time.

Tabled Study(s): N/A – none at this time

Adjourned Time: 11: 10 am