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## Periodic Review and Small Business Impact Review Report of Findings

<b>Agency name</b>	State Board of Social Services
<b>Virginia Administrative Code (VAC) Chapter citation(s)</b>	22 VAC40-890
<b>VAC Chapter title(s)</b>	Human Subject Research Regulations
<b>Date this document prepared</b>	8/1/2024

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

## Acronyms and Definitions

*Define all acronyms used in this Report, and any technical terms that are not also defined in the "Definitions" section of the regulation.*

CFR stands for Code of Federal Regulations  
COV stands for Code of Virginia  
VAC stands for Virginia Administrative Code

## Legal Basis

*Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.*

1) The promulgating agency is the State Board of Social Services, 2) upon the legal authority identified in § 63.2-218 of the Code of Virginia, 22VAC40-890, and 45 CFR 46, with 45 CFR 46 derived from three sections of the U.S. Code: 5 USC Section 301; 42 USC Section 289; and 42 USC Section 300v-1(b). Section 63.2-218 authorizes the State Board of Social Services to adopt regulations necessary relative to human research.

### Alternatives to Regulation

*Describe any viable alternatives for achieving the purpose of the regulation that were considered as part of the periodic review. Include an explanation of why such alternatives were rejected and why this regulation is the least burdensome alternative available for achieving its purpose.*

All proposed regulatory changes aim to clarify existing regulations in alignment with existing statute, and do not deviate substantially from existing Virginia and Federal code, regulations, guidance or practice.

### Public Comment

*Summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and provide the agency’s response. Be sure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency. Indicate if an informal advisory group was formed for purposes of assisting in the periodic review.*

Commenter	Comment	Agency response
	No comments received	

### Effectiveness

*Pursuant to § 2.2-4017 of the Code of Virginia, indicate whether the regulation meets the criteria set out in the ORM procedures, including why the regulation is (a) necessary for the protection of public health, safety, and welfare, and (b) is clearly written and easily understandable.*

This regulation requires that the Department of Social Services’ (DSS) Institutional Review Board (IRB) review and give its approval, as appropriate, to any research sponsored by DSS and related entities (i.e., local departments of social services, DSS-licensed facilities, and DSS-authorized contractors). The regulation is necessary for the public safety and welfare of human subjects involved in research sponsored by or approved through DSS and related entities. The regulation meets the criteria set out in EO 14 (2018), including being clearly written and easily understandable.

### Decision

*Explain the basis for the promulgating agency’s decision (retain the regulation as is without making changes, amend the regulation, or repeal the regulation).*

*If the result of the periodic review is to retain the regulation as is, complete the ORM Economic Impact form.*

While no public comments were received, regulatory language is not aligned with Code of Virginia. The decision is to amend the regulation, given that the Department of Social Services already has an action pending from 2021-2022 to accomplish that. The amendment was approved by the State Board of Social Services in December 2022. The amendment is still under review by the state Office of the Secretary of Health and Human Resources.

**Small Business Impact**

*As required by § 2.2-4007.1 E and F of the Code of Virginia, discuss the agency’s consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation; (3) the complexity of the regulation; (4) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, discuss why the agency’s decision, consistent with applicable law, will minimize the economic impact of regulations on small businesses.*

Universities and other external research organizations that wish to conduct human subject research involving DSS clients and/or use their administrative data may be exempt from all or some human research oversight (e.g., initial and continuing reviews), if the proposed study activities fall within certain categories that are likely to impose no risk or minimal risk to subjects.