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Periodic Review Report of Findings

Agency name	State Board of Social Services
Virginia Administrative Code (VAC) citation	22 VAC 40-890
Regulation title	Human Subject Research Regulations
Date this document prepared	August 21, 2019

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations*.

Acronyms and Definitions

Please define all acronyms used in this Report. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

VDSS Virginia Department of Social Services
IRB Institutional Review Board

Legal Basis

Please identify (1) the agency or other promulgating entity, 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 entity to regulate this specific subject or program, as well as a reference to the agency or promulgating entity's overall regulatory authority.

Section 63.2-218 authorizes the State Board of Social Services to adopt regulations necessary relative to human research. State authority is contained in § 63.2-218 of the Code of Virginia, as required by federal Title 45 CFR Part 46, Basic HHS Policy for Protection of Human Research Subjects. The federal authority

for 45 CFR 46 derives from three sections of the U.S. Code: 5 USC Section 301; 42 USC Section 289; and 42 USC Section 300v-1(b).

Alternatives

Please 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.

The state administrative regulation is required by the Code of Federal Regulations (i.e., Title 45 CFR Part 46), under the authority of three sections of the U.S. Code, identified under “Legal Basis,” above. The state is required to carry out the mandated federal regulation on human research protections. Therefore, no feasible alternatives were identified.

Public Comment

Please summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and provide the agency response. Ensure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency or board. Please indicate if an informal advisory group was formed for purposes of assisting in the periodic review.

No public comments were received.

Effectiveness

Pursuant to § 2.2-4017, please indicate whether the regulation meets the criteria set out in Executive Order 14 (as amended, July 16, 2018), 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

Please explain the basis for the rulemaking entity’s decision (retain the regulation as is without making changes, amend the regulation, or repeal the regulation).

While no public comments were received, regulatory language is not aligned with Code of Virginia. The recommendation is for a separate action to amend, at a future Board meeting. Amendments are needed to update definitions and other sections to conform to the Code of Virginia.

Small Business Impact

As required by § 2.2-4007.1 E and F of the Code of Virginia, include a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (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 the stated objectives of applicable law, will minimize the economic impact of regulations on small businesses.

There is no impact on small businesses. The regulation applies equally to all organizations conducting research through DSS and its related entities, whether public, non-profit, or private for-profit organizations. No complaints have been received from the public.