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Periodic Review and Small Business Impact Findings Where Result is "Retain the Regulation As Is"

Agency name	State Board of Social Services
Virginia Administrative Code (VAC) citation	22VAC40-890
Regulation title	Human Subject Research Regulations
Date	June 15, 2015

This information is required pursuant to Executive Order 17 (2014).

Legal basis

Please identify the state and/or federal legal authority for the regulation, including: 1) the most relevant law and/or regulation; and 2) promulgating entity, i.e., agency, board, or person.

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). Section 63.2-218 authorizes the State Board of Social Services to adopt regulations necessary relative to human research.

Alternatives

Please describe all viable alternatives for achieving the purpose of the existing regulation that have been considered as part of the periodic review process. Include an explanation of why such alternatives were rejected and why this regulation is the least burdensome alternative available for achieving the purpose of the regulation.

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. Please indicate if an informal advisory group was formed for purposes of assisting in the periodic review.

No comments received.

Effectiveness

Please indicate whether the regulation meets the criteria set out in Executive Order 17 (2014), e.g., is necessary for the protection of public health, safety, and welfare, and 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 17 (2014), including being clearly written and easily understandable.

Result

Please state that the reason why the agency is recommending that the regulation should stay in effect without change.

The agency recommends that 22VAC40-890 remain in effect, without change. For the reasons stated previously, the regulation is required. No comments were received and no necessary changes were identified during the periodic review.

Small business impact

In order to minimize the economic impact of regulations on small business, please include, pursuant to § 2.2-4007.1 E and F, 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, include a discussion of the basis for the agency's determination to retain the regulation as is, consistent with the stated objectives of applicable law, to 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