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Periodic Review and Small Business Impact Review Report of Findings

Agency name	Virginia Department of Behavioral Health and Developmental Services (DBHDS)
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC35-180
VAC Chapter title(s)	Regulations to Ensure the Protection of Participants in Human Research
Date this document prepared	March 20, 2023

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.

DBHDS – Department of Behavioral Health and Developmental Services
State Board – State Board of Behavioral Health and Developmental Services

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.

Section 37.2 -203 of the Code of Virginia authorizes the State Board to adopt regulations that may be necessary to carry out the provisions of Title 37.2 and other laws of the Commonwealth administered by the commissioner and the department.

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.

There are no viable alternatives to this regulation. Code of Virginia § 37.2-402 requires that the State Board adopt regulations regarding human research. The last revision effective in 2020 continue to hold the regulatory language fully in line with current requirements in federal regulation.

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.

One comment was received during the public comment period however the Department believes the comment was made in error as the comment simply stated “Period.” The Department reached out to the commenter to ask for clarification but received no response.

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.

As long as the Commonwealth allows human research, there is a continued need for the regulation. The regulation provides a straightforward framework for the conduct of research by any institution or agency as defined in the regulation (DBHDS, any community services board, or any facility or program operated, funded, or licensed by the department). The regulation incorporates but does not fully overlap, duplicate, or conflict with federal or state laws or regulations.

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.

The periodic review found that the regulations were reasonable and consistent with the statutory requirements, and all previous revisions (2020) continue to align with federal requirements.

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.

This regulation needs to remain in place to ensure the health, safety, and welfare of the individuals involved in human research. The only public comment received during the public comment period was not relevant to the regulations. The structure set out in the regulation is in accordance with other applicable federal and state laws and regulations. The regulation incorporates but does not fully overlap, duplicate, or conflict with federal or state laws or regulations. The last periodic review of the regulation was in 2018. Since that time, there have been no additional federal regulatory updates; therefore, this regulation should be maintained as it is currently in effect. The department plans to retain it as is. Since the previous periodic review, technology, economic conditions, or other factors have had no impact on Virginia's need for the regulation.
