

Office of Regulatory Management
Economic Review Form

Agency name	Virginia Department of Behavioral Health and Developmental Services (DBHDS)
Virginia Administrative Code (VAC) Chapter citation(s)	12 VAC 35-180
VAC Chapter title(s)	Regulations to Ensure the Protection of Participants in Human Research
Action title	Periodic Review
Date this document prepared	3/16/2023

Cost Benefit Analysis

Table 1a: Costs and Benefits of the Proposed Changes (Primary Option)

Omitted based on guidance from the ORM Regulatory Economic Analysis Manual (p. 3).

Table 1b: Costs and Benefits under the Status Quo (No change to the regulation)

Omitted based on guidance from the ORM Regulatory Economic Analysis Manual (p. 3).

Table 1c: Costs and Benefits under an Alternative Approach

Omitted based on guidance from the ORM Regulatory Economic Analysis Manual (p. 3).

Impact on Local Partners

Table 2: Impact on Local Partners

(1) Direct Costs & Benefits	Chapter 180, Regulations to Ensure the Protection of Subjects in Human Research, is only applicable to DBHDS, community services boards (CSBs), and any facility operated funded, or licensed by the Department that conducts research in which individuals participate as human subjects. As such, the only “Local Partners” that may be impacted by any regulatory change to this chapter are CSBs or private providers. No regulatory changes are planned as there have been no updates to federal regulations of human research since the final rule was published in 2018 and subsequent agency amendments that same year. As such, this regulation remains in compliance with federal requirements and will be retained as is.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) \$0

Direct Benefits	(b) \$0
(3) Indirect Costs & Benefits	
(4) Information Sources	Annotated Comparison of the Pre-2018 Common Rule with the Revised Common Rule: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/annotated-2018-requirements/index.html#46.104
(5) Assistance	
(6) Optional	

Economic Impacts on Families

Table 3: Impact on Families

(1) Direct Costs & Benefits	Chapter 180, Regulations to Ensure the Protection of Subjects in Human Research, is only applicable to DBHDS, CSBs, and any facility operated funded, or licensed by the Department that conducts research in which individuals participate as human subjects. Virginia families would only be impacted if a family member who is receiving or has received services were to participate as a subject in human research.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) \$0
Direct Benefits	(b) \$0
(3) Indirect Costs & Benefits	
(4) Information Sources	Annotated Comparison of the Pre-2018 Common Rule with the Revised Common Rule: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/annotated-2018-requirements/index.html#46.104

(5) Optional	
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Impacts on Small Businesses

Table 4: Impact on Small Businesses

(1) Direct Costs & Benefits	Chapter 180, Regulations to Ensure the Protection of Subjects in Human Research, is only applicable to DBHDS, CSBs, and any facility operated funded, or licensed by the Department that conducts research in which individuals participate as human subjects. Any small businesses impacted by this regulatory chapter would be facilities licensed by the Department. At this time the Department is not aware of any research being conducted or proposed from private providers; therefore, no costs or benefits are expected.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a) \$0
Direct Benefits	(b) \$0
(3) Indirect Costs & Benefits	
(4) Alternatives	No alternatives are available as the state regulations must be maintained with federal requirements.
(5) Information Sources	Annotated Comparison of the Pre-2018 Common Rule with the Revised Common Rule: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/annotated-2018-requirements/index.html#46.104
(6) Optional	

Changes to Number of Regulatory Requirements

For each individual VAC Chapter amended, repealed, or promulgated by this regulatory action, list (a) the initial requirement count, (b) the count of requirements that this regulatory package is adding, (c) the count of requirements that this regulatory package is reducing, (d) the net change in the number of requirements. This count should be based upon the text as written when this

stage was presented for executive branch review. Five rows have been provided, add or delete rows as needed.

Table 5: Total Number of Requirements

	Number of Requirements			
Chapter number	Initial Count	Additions	Subtractions	Net Change

This is an analysis of the current regulation following periodic review. The regulation will be retained as is.