

Office of Regulatory Management
Economic Review Form

Agency name	State Board of Social Services
Virginia Administrative Code (VAC) Chapter citation(s)	22 VAC 40-890
VAC Chapter title(s)	Human Subject Research Regulations
Action title	Periodic Review
Date this document prepared	5/1/2024
Regulatory Stage (including Issuance of Guidance Documents)	NA

Cost Benefit Analysis

Complete Tables 1a and 1b for all regulatory actions. You do not need to complete Table 1c if the regulatory action is required by state statute or federal statute or regulation and leaves no discretion in its implementation.

Table 1a should provide analysis for the regulatory approach you are taking. Table 1b should provide analysis for the approach of leaving the current regulations intact (i.e., no further change is implemented). Table 1c should provide analysis for at least one alternative approach. You should not limit yourself to one alternative, however, and can add additional charts as needed.

Report both direct and indirect costs and benefits that can be monetized in Boxes 1 and 2. Report direct and indirect costs and benefits that cannot be monetized in Box 4. See the ORM Regulatory Economic Analysis Manual for additional guidance.

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

(1) Direct & Indirect Costs & Benefits (Monetized)	Direct Costs: Describe the direct costs of this proposed change here. Indirect Costs: Describe the indirect costs of the proposed change. Direct Benefits: Describe the direct benefits of this proposed change here. Indirect Benefits: Describe the indirect benefits of the proposed change.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a)	(b)
(3) Net Monetized Benefit		
(4) Other Costs & Benefits (Non-Monetized)		
(5) Information Sources		

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

(1) Direct & Indirect Costs & Benefits (Monetized)	Direct Costs: Describe the direct costs of this proposed change here. Indirect Costs: Describe the indirect costs of the proposed change. Direct Benefits: Describe the direct benefits of this proposed change here. Indirect Benefits: Describe the indirect benefits of the proposed change.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a)	(b)
(3) Net Monetized Benefit		

(4) Other Costs & Benefits (Non-Monetized)	
(5) Information Sources	

Table 1c: Costs and Benefits under Alternative Approach(es)

(1) Direct & Indirect Costs & Benefits (Monetized)	Direct Costs: Describe the direct costs of this proposed change here. Indirect Costs: Describe the indirect costs of the proposed change. Direct Benefits: Describe the direct benefits of this proposed change here. Indirect Benefits: Describe the indirect benefits of the proposed change.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a)	(b)
(3) Net Monetized Benefit		
(4) Other Costs & Benefits (Non-Monetized)		
(5) Information Sources		

Impact on Local Partners

Use this chart to describe impacts on local partners. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

NOTE: A fast track regulation to update this chapter was initiated in 2022 and is pending with the Office of Secretary of Health and Human Resources. The proposed changes are intended to align state regulations with federal regulations.

Table 2: Impact on Local Partners

(1) Direct & Indirect Costs &	Direct Costs: Describe the direct costs of this proposed change here. Indirect Costs: Describe the indirect costs of the proposed change.
-------------------------------	--

Benefits (Monetized)	<p>Direct Benefits: Describe the direct benefits of this proposed change here.</p> <p>Indirect Benefits: Describe the indirect benefits of the proposed change.</p>	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) There are no direct or indirect costs for local Partners, including other government entities.	(b) There are no direct or indirect benefits for local partners, including other government entities.
(3) Other Costs & Benefits (Non-Monetized)	<p>Local departments of social services (LDSS) that wish to conduct human subject research involving DSS clients and/or use of their administrative data may be exempt from all or some human research oversight (e.g., initial and continuing reviews) conducted by the VDSS Institutional Review Board (IRB) if the proposed study activities fall within certain categories that are likely to impose no risk or minimal risk to subjects.</p>	
(4) Assistance		
(5) Information Sources	<p>This regulation applies to the LDSS if they are conducting human subject research. The VDSS IRB does not charge any fees to the LDSS for IRB reviews and oversight. There is no anticipated economic impact on these agencies.</p>	

Impacts on Families

Use this chart to describe impacts on families. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

Table 3: Impact on Families

(1) Direct & Indirect Costs & Benefits (Monetized)	<p>Direct Costs: Describe the direct costs of this proposed change here.</p> <p>Indirect Costs: Describe the indirect costs of the proposed change.</p> <p>Direct Benefits: Describe the direct benefits of this proposed change here.</p> <p>Indirect Benefits: Describe the indirect benefits of the proposed change.</p>	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits

	(a) There are no direct or indirect costs for Families.	(b) There are no direct or indirect benefits for Families.
(3) Other Costs & Benefits (Non-Monetized)	None.	
(4) Information Sources		

Impacts on Small Businesses

Use this chart to describe impacts on small businesses. See Part 8 of the ORM Cost Impact Analysis Guidance for additional guidance.

Table 4: Impact on Small Businesses

(1) Direct & Indirect Costs & Benefits (Monetized)	<p>Direct Costs: Describe the direct costs of this proposed change here.</p> <p>Indirect Costs: Describe the indirect costs of the proposed change.</p> <p>Direct Benefits: Describe the direct benefits of this proposed change here.</p> <p>Indirect Benefits: Describe the indirect benefits of the proposed change.</p>	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) There are no direct or indirect monetary costs for Small Businesses.	(b) There are no direct or indirect monetary benefits for Small Businesses.
(3) Other Costs & Benefits (Non-Monetized)	Universities and other external research organizations that wish to conduct human subject research involving DSS clients and/or use of their administrative data may be exempt from all or some human research oversight (e.g., initial and continuing reviews) conducted by the VDSS Institutional Review Board (IRB) if the proposed study activities fall within certain categories that are likely to impose no risk or minimal risk to subjects.	
(4) Alternatives		
(5) Information Sources	VDSS does not collect information on the small business status of these organizations. Furthermore, the VDSS IRB does not charge any fees to these organizations for IRB reviews and oversight. There is no anticipated economic impact on these organizations.	

Changes to Number of Regulatory Requirements

Table 5: Regulatory Reduction

For each individual action, please fill out the appropriate chart to reflect any change in regulatory requirements, costs, regulatory stringency, or the overall length of any guidance documents.

Change in Regulatory Requirements

VAC Section(s) Involved*	Authority of Change	Initial Count	Additions	Subtractions	Total Net Change in Requirements
	(M/A):				
	(D/A):				
	(M/R):				
	(D/R):				
Grand Total of Changes in Requirements:					(M/A):
					(D/A):
					(M/R):
					(D/R):

Key:

Please use the following coding if change is mandatory or discretionary and whether it affects externally regulated parties or only the agency itself:

(M/A): Mandatory requirements mandated by federal and/or state statute affecting the agency itself

(D/A): Discretionary requirements affecting agency itself

(M/R): Mandatory requirements mandated by federal and/or state statute affecting external parties, including other agencies

(D/R): Discretionary requirements affecting external parties, including other agencies

Cost Reductions or Increases (if applicable)

VAC Section(s) Involved*	Description of Regulatory Requirement	Initial Cost	New Cost	Overall Cost Savings/Increases

Other Decreases or Increases in Regulatory Stringency (if applicable)

VAC Section(s) Involved*	Description of Regulatory Change	Overview of How It Reduces or Increases Regulatory Burden

Length of Guidance Documents (only applicable if guidance document is being revised)

Title of Guidance Document	Original Word Count	New Word Count	Net Change in Word Count

*If the agency is modifying a guidance document that has regulatory requirements, it should report any change in requirements in the appropriate chart(s).