

Office of Regulatory Management  
Economic Review Form

<b>Agency name</b>	State Board of Education
<b>Virginia Administrative Code (VAC) Chapter citation(s)</b>	8VAC20-565
<b>VAC Chapter title(s)</b>	Regulations for the Protection of Students as Participants in Human Research
<b>Action title</b>	Periodic Review
<b>Date this document prepared</b>	May 20, 2024
<b>Regulatory Stage (including Issuance of Guidance Documents)</b>	Periodic Review

### **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)	<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)	(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.

**Table 2: Impact on Local Partners**

(1) Direct & Indirect Costs & Benefits (Monetized)	<p>The regulatory chapter prohibits the Board and any public school from conducting any human research involving students unless it is in compliance with this chapter and any other relevant law. First, the chapter requires that any student involved in human research provide their, as well their parents or legally authorized representative, informed consent. Such informed consent should be in writing on a form which meets the criteria of Va. Code § 32.1-162.18. Any human research must</p>
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<p>be approved and conducted under the review of a human research committee. Any such committee must comply with the provisions of Va. Code § 32.1-162.19. Such committees must at least annually report to the Governor, the General Assembly, and the Superintendent of Public Instruction (or their designee) any projects they have reviewed and approved, as well as any significant deviations from the proposals as they were approved. Lastly, the chapter states that any of the categories listed in Va. Code § 32.1-162.17 are exempt from this chapter.</p> <p>Costs: There are no costs being imposed on local partners. This chapter reflects the statutory mandate found in Va. Code § 32.1-162.16 et seq.</p> <p>Benefits: This chapter ensures that any human research conducted by a school is done within the bounds of certain guidelines. This ensures the safety and integrity of any research that may be conducted under the chapter.</p>		
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a)	(b)
(3) Other Costs & Benefits (Non-Monetized)		
(4) Assistance		
(5) Information Sources		

**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>This chapter regulates public schools and the Board, not students or families themselves.</p> <p>Costs: There are no costs being imposed on families.</p>
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	Benefits: This chapter benefits families by ensuring that students are not involved in or subject to human research outside the bounds of what the chapter allows.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a)	(b)
(3) Other Costs & Benefits (Non-Monetized)		
(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)	This chapter does not regulate small business.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a)	(b)
(3) Other Costs & Benefits (Non-Monetized)		
(4) Alternatives		
(5) Information Sources		

**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):				
<b>Grand Total of Changes in Requirements:</b>					(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)*

<b>Title of Guidance Document</b>	<b>Original Word Count</b>	<b>New Word Count</b>	<b>Net Change in Word Count</b>

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