

Office of Regulatory Management  
Economic Review Form

<b>Agency name</b>	Virginia Department of Social Services
<b>Virginia Administrative Code (VAC) Chapter citation(s)</b>	22 VAC 40-890
<b>VAC Chapter title(s)</b>	Human Subject Research Regulations
<b>Action title</b>	Update Human Subject Research Chapter
<b>Date this document prepared</b>	September 29, 2022

**Cost Benefit Analysis**

Table 1a must be completed for all actions. Tables 1b and 1c must be completed for actions (or portions thereof) where the agency is exercising discretion, including those where some of the changes are mandated by state or federal law or regulation. Tables 1b and 1c are not needed if **all** changes are mandated, and the agency is not exercising any discretion. In that case, enter a statement to that effect.

- (1) Direct Costs & Benefits: Identify all specific, direct economic impacts (costs and/or benefits), anticipated to result from the regulatory change. (A direct impact is one that affects entities regulated by the agency and which directly results from the regulatory change itself, without any intervening steps or effects. For example, the direct impact of a regulatory fee change is the change in costs for these regulated entities.) When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Keep in mind that this is the proposed change versus the status quo. One bullet has been provided, add additional bullets as needed.
- (2) Quantitative Factors:
  - (a) Enter estimated dollar value of total (overall) direct costs described above.
  - (b) Enter estimated dollar value of total (overall) direct benefits described above.
  - (c) Enter the present value of the direct costs based on the worksheet.
  - (d) Enter the present value of the direct benefits based on the worksheet.
- (3) Benefits-Costs Ratio: Calculate d divided by c OR enter it from the worksheet.
- (4) Net Benefit: Calculate d minus c OR enter it from the worksheet.
- (5) Indirect Costs & Benefits: Identify all specific, indirect economic impacts (costs and/or benefits), anticipated to result from the regulatory change. (An indirect impact is one that results from responses to the regulatory change, but which are not directly required by the regulation. Indirect impacts of a regulatory fee change on regulated entities could include a change in the prices they charge, changes in their operating procedures or employment levels, or decisions to enter or exit the regulated profession or market. Indirect impacts also include responses by other entities that have close economic ties to the regulated entities, such as suppliers or partners.) If there are no indirect costs or benefits, include a specific statement to that effect.

- (6) Information Sources: Describe the sources of information used to determine the benefits and costs, including the source of the Quantitative Factors. If dollar amounts are not available, indicate why they are not.
- (7) Optional: Use this space to add any further information regarding the data provided in this table, including calculations, qualitative assessments, etc.

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

(1) Direct Costs & Benefits	<ul style="list-style-type: none"> <li>The proposed changes are to align language (definitions, terms) in the chapter with other Virginia codes (e.g., § 32.1-162.19). The proposed changes update specific requirements in the chapter to align with federal regulations on human subject research protections in 45 CFR 46.</li> <li>Both human research review committees (also known as institutional review boards, or IRBs) and research organizations that conduct human subjects research are required to register with the U.S. Office for Human Research Protections and must comply with current federal regulations in 45 CFR 46.</li> <li>The intent of the federal regulations is to reduce administrative burden by making certain types of low-risk research either eligible for exemption from IRB review or eligible for expedited review by the IRB Chair in lieu of a review by the convened IRB (full board review).</li> <li>There is no direct economic cost or benefit from the proposed changes. The VDSS IRB does not charge fees to researchers for IRB reviews and other determinations. IRB members are not paid for their service. VDSS does not have a FTE dedicated to managing operations in the IRB. Coordination of the IRB is an unfunded activity.</li> </ul>		
(2) Quantitative Factors	Estimated Dollar Amount	Present Value	
Direct Costs	(a)	(c)	
Direct Benefits	(b)	(d)	
(3) Benefits-Costs Ratio		(4) Net Benefit	
(5) Indirect Costs & Benefits	There are no indirect economic costs or benefits in terms of fees or FTEs associated with these changes to the chapter. The non-monetary benefits are that it may possibly reduce the number of expedited or full board reviews conducted by the IRB.		

(6) Information Sources	
(7) Optional	

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

*This table addresses current requirements and the implications of not making any changes. In other words, describe the costs and benefits of maintaining the current regulatory requirements as is.*

(1) Direct Costs & Benefits	<ul style="list-style-type: none"> <li>All changes in the state regulations are mandated, in order to stay in compliance with federal regulations in 45 CFR 46. The agency is not exercising any discretion in adding provisions.</li> </ul>		
(2) Quantitative Factors	Estimated Dollar Amount	Present Value	
Direct Costs	(a)	(c)	
Direct Benefits	(b)	(d)	
(3) Benefits-Costs Ratio		(4) Net Benefit	
(5) Indirect Costs & Benefits			
(6) Information Sources			
(7) Optional			

**Table 1c: Costs and Benefits under an Alternative Approach**

*This table addresses an alternative approach to accomplishing the objectives with different requirements. These alternative approaches may include the use of reasonably available alternatives in lieu of regulation, or information disclosure requirements or performance standards instead of regulatory mandates.*

(1) Direct Costs & Benefits	<ul style="list-style-type: none"> <li>• <b>Describe first alternative proposed impactful change here.</b></li> </ul> <p>Direct Costs: Describe the direct costs of this proposed change here.</p> <p>Direct Benefits: Describe the direct benefits of this proposed change here.</p> <ul style="list-style-type: none"> <li>• Use additional bullets as needed</li> </ul>		
(2) Quantitative Factors	Estimated Dollar Amount	Present Value	
Direct Costs	(a)	(c)	
Direct Benefits	(b)	(d)	
(3) Benefits-Costs Ratio		(4) Net Benefit	
(5) Indirect Costs & Benefits			
(6) Information Sources			
(7) Optional			

**Impact on Local Partners**

- (1) Describe the direct costs and benefits (as defined on page 1) for local partners in terms of real monetary costs and FTEs. Local partners include local or tribal governments, school divisions, or other local or regional authorities, boards, or commissions. If local partners are not affected, include a specific statement to that effect and a brief explanation of the rationale.
- (2) Quantitative Factors:
  - (a) Enter estimated dollar value of total (overall) direct costs described above.
  - (b) Enter estimated dollar value of total (overall) direct benefits described above.
- (3) Indirect Costs & Benefits: Describe any indirect benefits and costs (as defined on page 1) for local partners that are associated with all significant changes. If there are no indirect costs or benefits, include a specific statement to that effect.

- (4) Information Sources: describe the sources of information used to determine the benefits and costs, including the source of the Quantitative Factors. If dollar amounts are not available, indicate why they are not.
- (5) Assistance: Identify the amount and source of assistance provided for compliance in both funding and training or other technical implementation assistance.
- (6) Optional: Use this space to add any further information regarding the data provided in this table, including calculations, qualitative assessments, etc.

Note: If any of the above information was included in Table 1, use the same information here.

**Table 2: Impact on Local Partners**

(1) Direct Costs & Benefits	There is no direct economic impact in terms of costs and FTEs for Local Partners, including other government entities.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a)
Direct Benefits	(b)
(3) Indirect Costs & Benefits	There is no indirect economic impact in terms of costs and FTEs for Local Partners, including other government entities.
(4) Information Sources	
(5) Assistance	
(6) Optional	

**Economic Impacts on Families**

- (1) Describe the direct costs and benefits (as defined on page 1) to a typical family of three (average family size in Virginia according to the U. S. Census) arising from any proposed regulatory changes that would affect the costs of food, energy, housing, transportation, healthcare, and education. If families are not affected, include a specific statement to that effect and a brief explanation of the rationale.
- (2) Quantitative Factors:
  - (a) Enter estimated dollar value of direct costs.
  - (b) Enter estimated dollar value of direct benefits.

- (3) Indirect Costs & Benefits: Describe any indirect costs and benefits (as defined on page 1) to a typical family of three that are most likely to result from the proposed changes.
- (4) Information Sources: describe the sources of information used to determine the benefits and costs, including the source of the Quantitative Factors. If dollar amounts are not available, indicate why not.
- (5) Optional: Use this space to add any further information regarding the data provided in this table, including calculations, qualitative assessments, etc.

Note: If any of the above information was included in Table 1, use the same information here.

**Table 3: Impact on Families**

(1) Direct Costs & Benefits	There is no direct economic impact to families in Virginia.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a)
Direct Benefits	(b)
(3) Indirect Costs & Benefits	There is no indirect economic impact to families in Virginia.
(4) Information Sources	
(5) Optional	

**Impacts on Small Businesses**

- (1) Describe the direct costs and benefits (as defined on page 1) for small businesses. For purposes of this analysis, “small business” means the same as that term is defined in § 2.2-4007.1. If small businesses are not affected, include a specific statement to that effect and a brief explanation of the rationale.
- (2) Quantitative Factors:
  - (a) Enter estimated dollar value of direct costs.
  - (b) Enter estimated dollar value of direct benefits.
- (3) Indirect Costs & Benefits: Describe the indirect benefits and costs (as defined on page 1) for small businesses that are most likely to result from the proposed changes.

- (4) Alternatives: Add a qualitative discussion of any equally effective alternatives that would make the regulatory burden on small business more equitable compared to other affected business sectors, and how those alternatives were identified.
- (5) Information Sources: describe the sources of information used to determine the benefits and costs, including the source of the Quantitative Factors. If dollar amounts are not available, indicate why not.
- (6) Optional: Use this space to add any further information regarding the data provided in this table, including calculations, qualitative assessments, etc.

Note: If any of the above information was included in Table 1, use the same information here.

**Table 4: Impact on Small Businesses**

(1) Direct Costs & Benefits	Universities and other external research organizations that conduct human subjects research may benefit from these regulatory changes. On average, per year, the VDSS IRB receives submissions from 10 researchers/research organizations. However, 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 other determinations. There is no anticipated economic impact on these organizations.
(2) Quantitative Factors	Estimated Dollar Amount
Direct Costs	(a)
Direct Benefits	(b)
(3) Indirect Costs & Benefits	Universities and other organizations that are conducting human subjects research involving DSS clients and/or administrative data may indirectly benefit from these regulatory changes by having fewer requirements to submit low-risk studies to the IRB for expedited or full board review.
(4) Alternatives	
(5) Information Sources	
(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
22VAC40-890	1	0	0	0