

Office of Regulatory Management
Economic Review Form

Agency name	Virginia Department of Social Services
Virginia Administrative Code (VAC) Chapter citation(s)	22 VAC 40-890
VAC Chapter title(s)	Human Subject Research Regulations
Action title	Update Human Subject Research Chapter
Date this document prepared	12/2/2024
Regulatory Stage (including Issuance of Guidance Documents)	Fast-Track

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)	<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) None.	(b) None.
(3) Net Monetized Benefit		
(4) Other Costs & Benefits (Non-Monetized)	<ul style="list-style-type: none"> • The proposed changes borrow language (terms and definitions) used in other Virginia codes (e.g., § 32.1-162.19) and update specific sections in the chapter to align with the newer federal regulations on human subject research protections (45 CFR 46). • 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 comply with federal regulations in 45 CFR 46. • The intent behind updating 45 CFR 46 in 2019 was to make more low-risk research activities eligible for either expedited review or exemption from IRB oversight and thus reduce the administrative burden on both the researcher and the IRB. (In an expedited review, the Chairperson and one other IRB member conduct the review. In comparison, a full board review involves all IRB members.) The proposed changes may reduce the number of expedited and full board reviews conducted by the IRB. • There is no direct economic cost or benefit from the proposed changes. The VDSS IRB does not charge fees to researchers for IRB oversight. IRB members are not paid for their services. VDSS does not have a FTE dedicated to managing operations in the IRB. Coordination of the IRB is an unfunded activity. 	
(5) Information Sources		

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

(1) Direct & Indirect Costs & Benefits	<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>	
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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) None.	(b) None.
(3) Net Monetized Benefit		
(4) Other Costs & Benefits (Non-Monetized)	<p>Under the Status Quo, the VDSS IRB would be out of compliance with the federal regulations (45 CFR 46). All proposed changes are mandated, per federal regulations in 45 CFR 46. The agency is not exercising any discretion in adding provisions.</p>	
(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	
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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>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 local Partners, including other government entities.	(b) There are no direct or indirect costs 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 IRB if the proposed study activities fall within certain categories that are likely to impose minimal or no 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)	There is no non-monetary impact on families from the proposed changes.	
(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.

<p>(3) Other Costs & Benefits (Non-Monetized)</p>	<p>The proposed changes apply to universities and other external research organizations that wish to conduct human subject research involving DSS clients and/or use of their administrative data. (VDSS does not collect information on the small business status of these groups.) These organizations may be exempt from all or some human research protection oversight (e.g., initial and continuing reviews) conducted by the VDSS IRB if the proposed study activities fall within certain categories that are likely to impose no risk or minimal risk to subjects.</p>
<p>(4) Alternatives</p>	
<p>(5) Information Sources</p>	<p>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.</p>

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 Involved*	Authority of Change	Initial Count	Additions	Subtractions	Total Net Change in Requirements
22VAC40-890-10	(M/A):	0	0		0
	(D/A):	0	0		0
	(M/R):	0	0		0
	(D/R):	0	0		0

VAC Section Involved*	Authority of Change	Initial Count	Additions	Subtractions	Total Net Change in Requirements
22VAC40-890-20	(M/A):	0	0		0
	(D/A):	0	0		0
	(M/R):	0	0		0
	(D/R):	0	0		0

VAC Section Involved*	Authority of Change	Initial Count	Additions	Subtractions	Total Net Change in Requirements
22VAC40-890-30	(M/A):	0	0		0
	(D/A):	0	0		0
	(M/R):	0	0		0
	(D/R):	0	0		0

VAC Section Involved*	Authority of Change	Initial Count	Additions	Subtractions	Total Net Change in Requirements
22VAC40-890-40	(M/A):	4	0		0
	(D/A):	0	0		0
	(M/R):	11	0		0
	(D/R):	0	0		0

VAC Section Involved*	Authority of Change	Initial Count	Additions	Subtractions	Total Net Change in Requirements
	(M/A):	0	0		0
	(D/A):	0	0		0

22VAC40-890-50	(M/R):	5	0		0
	(D/R):	0	0		0

VAC Section Involved*	Authority of Change	Initial Count	Additions	Subtractions	Total Net Change in Requirements
22VAC40-890-60	(M/A):	9	0		0
	(D/A):	0	0		0
	(M/R):	1	0		0
	(D/R):	0	0		0

VAC Section Involved*	Authority of Change	Initial Count	Additions	Subtractions	Total Net Change in Requirements
22VAC40-890-70	(M/A):	11	0		0
	(D/A):	1	0		0
	(M/R):	10	0		0
	(D/R):	0	0		0

VAC Section Involved*	Authority of Change	Initial Count	Additions	Subtractions	Total Net Change in Requirements
22VAC40-890-80	(M/A):	2	5		5
	(D/A):	0	0		0
	(M/R):	0	0		0
	(D/R):	0	0		0

VAC Section Involved*	Authority of Change	Initial Count	Additions	Subtractions	Total Net Change in Requirements
22VAC40-890-90	(M/A):	9	0		0
	(D/A):	0	0		0
	(M/R):	3	0		0
	(D/R):	0	0		0

VAC Section Involved*	Authority of Change	Initial Count	Additions	Subtractions	Total Net Change in Requirements
22VAC40-890-100	(M/A):	9	0		0
	(D/A):	0	0		0
	(M/R):	0	0		0
	(D/R):	0	0		0

Use this table to add total net changes in requirements of all sections involved (if only one section changed-add total of the one section).	Grand Total of All Changes in Requirements:	(M/A): +5
		(D/A): 0
		(M/R): 0
		(D/R): 0

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
22VAC40-890-10	Align definitions to be consistent with those in other State code	No increase in regulatory burden
22VAC40-890-20	Remove outdated language	No increase in regulatory burden
22VAC40-890-30	Align state requirements with federal regulation re: exempt research	No increase in regulatory burden
22VAC40-890-40	Minor changes to wording	No increase in regulatory burden
22VAC40-890-50	Minor changes to wording	No increase in regulatory burden
22VAC40-890-60	Minor changes to wording; reduce the required number of members on the research review committee	No increased burden. This change aligns state regulations with federal code.

22VAC40-890-70	Add language re: annual continuing review for ongoing studies	No increased burden. This aligns with the federal code and current practice by the IRB.
22VAC40-890-80	Provides more guidance re: expedited review process	Aligns state regulations with federal code. Additional types of research may qualify for expedited vs. full board review.
22VAC40-890-90	Elaborates about reporting requirements	No increased regulatory burden.
22VAC40-890-100	No change	

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).