Office of Regulatory Management

Economic Review Form

Agency name	Virginia Department for Aging and Rehabilitative Services
Virginia Administrative Code (VAC) Chapter citation(s)	22 VAC 30-40
VAC Chapter title(s)	Protections of Participants in Human Research
Action title	Periodic Review
Date this document prepared	May 8, 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.

As mandated by federal law and regulation (e.g., 45 CFR Part 46 and 34 CFR Part 97) and state law (see § 51.5-132 of the Code of Virginia), the Protections of Participants in Human Research regulation (22VAC30-40) establishes protocols to approve research proposals involving of the Department for Aging and Rehabilitative Services (DARS), including Wilson Workforce and Rehabilitation Center (WWRC), and DARS' providers, specifically the area agencies on aging (AAAs), sheltered workshops (i.e., employment services organizations) and centers for independent living (CILs). These required protocols ensure adequate safeguards for the rights and welfare of individuals participating in human subject research and ensure such safeguards are consistent with federal requirements and state laws obligations.

Last fiscal year, the DARS, Human Research Review Committee (HRRC) reviewed eight research projects, of which one was approved, four were amended or continued, and the remaining four were closed/wrapped up. During fiscal year 2022-23, the HRRC reviewed eleven projects, of which three were approved, four were amended or continued, and four were closed/wrapped up.

The purpose of this periodic review is to determine whether this regulation should be repealed, amended, or retained in its current form. Public comment is sought on the review of any issue relating to this regulation, including whether the regulation (i) is necessary for the protection of public health, safety, and welfare or for the efficient performance of important governmental functions; (ii) minimizes the economic impact on small businesses in a manner consistent with the stated objectives of applicable law; and (iii) is clearly written and easily understandable.

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

(1) Direct & Indirect Costs & Benefits (Monetized)	There are no proposed changes to this regulation.	
(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) There are no direct or indirect costs under the status quo.	(b) There are no direct or indirect costs under the status quo.
(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)	There are no alternative approaches.	
(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)	There is no impact on local partners. 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) 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)	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) 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)	22VAC30-40 provides important safeguards to human subjects who are asked to and decide to participate in research. Since DARS and its providers serve individuals with disabilities and older adults, these protections are particularly important to ensuring that individuals are not pressured into participating, and that their rights and safety are protected during all human subject research.	
(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)	While WWRC is an extension of DARS, the AAAs, sheltered workshops, and CILs would be considered small businesses. 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) There are no direct or indirect monetary costs for small businesses.	(b) There are no direct or indirect benefits for small businesses.
(3) Other Costs & Benefits (Non-Monetized)	DARS, WWRC, AAAs, sheltered workshops, and CILs that conduct or participate in human subject research would be subject to these provisions as required by federal and state law. Universities and other external research organizations that partner with DARS, WWRC, AAAs, sheltered workshops, and CILs in conducting human subject research would also be subject to these provisions as required by federal and state	

	law. DARS does not charge fees for reviews or oversight and often uses develops Institutional Review Board (IRB) Authorization Agreements with universities for the primary review and approval of human subject research, thus minimizing the burden on these entities for the DARS' HRRC review and approval process. There is no anticipated economic impact on these entities for this regulation.
(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):				
				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).