Office of Regulatory Management

Economic Review Form

Agency name	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	Human Research Procedures Manual Update
Date this document prepared	October 3, 2024
Regulatory Stage (including Issuance of Guidance Documents)	Guidance Document Update

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.

Background:
As mandated by federal law and regulation (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 the Department for Aging and Rehabilitative Services (DARS), including Wilson Workforce and Rehabilitation Center (WWRC), and DARS' affiliated providers, specifically the area agencies on aging (AAAs), sheltered workshops (i.e., employment services organizations or ESOs) 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.

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

The purpose of this guidance document update is to clarify that in situations when a joint review arrangement is not possible for a cooperative research project, the covered entity (DARS, WWRC, AAAs, sheltered workshops or CILs) may submit to the DARS HRRC a research application prepared for the other IRB institution and the DARS HRRC will follow the applicable review protocol to determine if it complies with DARS' research requirements. Providing this option, streamlines the review process by eliminating the need for the covered entity to prepare two separate and different applications when participating in a cooperative research project.

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

(1) Direct & Indirect Costs & Benefits (Monetized)	There are no costs associated with the proposed changes. DARS does not charge a fee for reviews of research projects. Direct Costs: $0 Indirect Costs: $0 Direct Benefits: $0 Indirect Benefits: While DARS is not able to identify specific cost savings associated with this change, we anticipate the change will reduce the burden (e.g., time spent) covered entities experience in obtaining approvals for cooperative research projects.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits

	(a) $0	(b) $0
(3) Net Monetized Benefit	While DARS is not able to identify specific cost savings associated with this change, we anticipate the change will reduce the burden (e.g., time spent) covered entities experience in obtaining approvals for cooperative research projects.	
(4) Other Costs & Benefits (Non-Monetized)	Ensuring Human Research Procedures Manual filed on the Town Hall website is updated and consistent with current state law, federal law, and DARS procedures provides DARS, DARS' covered entities, and the public with clear and accessible information. This advances ORM's goals of streamlined access and transparency.	
(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: $0 Indirect Costs: While DARS is not able to identify a specific cost associated with the status quo, we can assume that not including clarifying language for cooperative research projects would require covered entities to complete two applications for one project instead of just one, which duplicates efforts and increases the burden (e.g., time spent) on covered entities. Direct Benefits: $0 Indirect Benefits: $0	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Net Monetized Benefit	$0	
(4) Other Costs & Benefits (Non-Monetized)	If the Human Research Procedures Manual is not updated on Town Hall to reflect best practices and requirements, it has the potential to create confusion among DARS staff, covered entities, and the public, and runs contrary to ORM's goals of streamlined access and transparency.	

(5) Information Sources	

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

(1) Direct & Indirect Costs & Benefits (Monetized)	There are no alternative approaches that would allow DARS to permit this streamlined process. 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.

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)	The Human Research Procedures regulations and accompanying Human Research Procedures Manual provide important safeguards to human subjects who are asked to and decide to participate in research. Since DARS and the covered entities 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. There are no impacts on families associated with this change. Direct Costs: $0 Indirect Costs: $0 Direct Benefits: $0 Indirect Benefits: $0

(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) $0
(3) Other Costs & Benefits (Non-Monetized)	Ensuring Human Research Procedures Manual filed on the Town Hall website is updated and consistent with current state law, federal law, and DARS procedures provides DARS, DARS' covered entities, and the public with clear and accessible information. This advances ORM's goals of streamlined access and transparency.	
(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)	AAAs, CILs and ESOs (as well as DARS and WWRC) partner with state universities and colleges, and other public agencies to conduct research studies. State universities and colleges and other public agencies are considered local partners. Last fiscal year, the DARS HRRC reviewed nine research projects, of which one was approved, four were amended or continued, and the remaining four were completed. During fiscal year 2022-23, the HRRC reviewed eleven projects, of which three were approved, four were amended or continued, and four were completed. DARS does not charge fees for HHRC reviews or oversight. There is no anticipated economic impact on local partners; if anything, this change helps entities by streamlining the application and review process for cooperative research projects. Direct Costs: $0 Indirect Costs: $0 Direct Benefits: $0 Indirect Benefits: While DARS is not able to identify specific cost savings associated with this change, we anticipate the change will reduce

	the burden (e.g., time spent) covered entities experience in obtaining approvals for cooperative research projects.	
(2) Present Monetized Values	Direct & Indirect Costs	Direct & Indirect Benefits
	(a) $0	(b) While DARS is not able to identify specific cost savings associated with this change, we anticipate the change will reduce the burden (e.g., time spent) covered entities experience in obtaining approvals for cooperative research projects.
(3) Other Costs & Benefits (Non-Monetized)	Ensuring Human Research Procedures Manual filed on the Town Hall website is updated and consistent with current state law, federal law, and DARS procedures provides DARS, DARS' covered entities, and the public with clear and accessible information. This advances ORM's goals of streamlined access and transparency.	
(4) Alternatives	N/A	
(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**
Protections of Participants in Human Research	33 pages 11,014 words	33 pages 11,014 words	0 pages 0 words

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