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Periodic Review and Small Business Impact Review Report of Findings

Agency name	Virginia Department of Aging and Rehabilitative Services (DARS)
Virginia Administrative Code (VAC) Chapter citation(s)	22VAC30-40
VAC Chapter title(s)	Protections of Participants in Human Research
Date this document prepared	August 16, 2024

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code.*

Acronyms and Definitions

Define all acronyms used in this Report, and any technical terms that are not also defined in the "Definitions" section of the regulation.

AAA – Area Agency on Aging
CIL – Center for Independent Living
HRRC – Human Research Review Committee
WWRC – Wilson Workforce & Rehabilitation Center

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Section 51.5-132 of the Code of Virginia authorizes the Commissioner of DARS to promulgate regulations necessary to carry out human research, to be conducted or authorized by DARS, any AAA, any sheltered workshop (also known as an employment services organization), any CIL, or WWRC.

Alternatives to Regulation

Describe any viable alternatives for achieving the purpose of the regulation that were considered as part of the periodic review. Include an explanation of why such alternatives were rejected and why this regulation is the least burdensome alternative available for achieving its purpose.

There are no viable alternatives for achieving the purpose of the regulation. This regulation is required by the Code of Virginia.

Public Comment

Summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and provide the agency's response. Be sure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency. Indicate if an informal advisory group was formed for purposes of assisting in the periodic review.

Commenter	Comment	Agency response
NA	NA	NA

Effectiveness

Pursuant to § 2.2-4017 of the Code of Virginia, indicate whether the regulation meets the criteria set out in the ORM procedures, including why the regulation is (a) necessary for the protection of public health, safety, and welfare, and (b) is clearly written and easily understandable.

The Protections of Participants in Human Research regulation (22VAC30-40) establishes protocols to ensure adequate safeguards for the rights and welfare of individuals participating in human subject research.

DARS, WWRC, AAAs, sheltered workshops (or employment services organizations), and CILs that conduct or participate in human subject research are 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. DARS, WWRC, and the agency's affiliated providers conduct human subject research projects that involve older adults and individuals with disabilities, including youth with disabilities.

The regulation meets the criteria set out in Executive Order 19 (2022) as it safeguards the health, welfare, and safety of these individuals during such research activities.

The regulation is clearly written and understandable.

Decision

Explain the basis for the promulgating agency's decision (retain the regulation as is without making changes, amend the regulation, or repeal the regulation).

If the result of the periodic review is to retain the regulation as is, complete the ORM Economic Impact form.

The periodic review determined that the regulation should be retained as is.

Small Business Impact

As required by § 2.2-4007.1 E and F of the Code of Virginia, discuss the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, discuss why the agency's decision, consistent with applicable law, will minimize the economic impact of regulations on small businesses.

The regulation is necessary to comply with § 51.5-132 of the Code of Virginia, and to protect the health, welfare, and safety of older adults and individuals with disabilities, including youth with disabilities, who participate in research projects conducted by DARS, WWRC, and the agency's affiliated providers.

DARS has not received any complaints or concerns about the regulatory chapter.

Following the promulgation of the federal "Common Rule" in 2018, DARS updated the regulatory chapter to align with federal requirements in 2020. The regulation does not conflict with any federal laws or regulations or state laws.

As a result of Chapter 728 of the 2020 Acts of Assembly, the chapter was revised in 2020 to include AAAs under the scope of the regulation.

There is no anticipated economic impact on these entities for this regulation. DARS does not charge fees for HHRC reviews or oversight. Through this regulatory chapter, DARS aligns the agency's requirements with those that are expected through the Common Rule for all research conducted using federal funding. This alignment streamlines the review and approval process for researchers. Further, DARS is often able to defer to Institutional Review Boards (IRBs) within universities as the primary reviewer and approver of human subject research, which minimizes burden and eliminates redundancy for the DARS' HRRC as well as for researchers.