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Periodic Review Report of Findings

Agency name	Virginia Department for Aging and Rehabilitative Services
Virginia Administrative Code (VAC) citation	22VAC30-40
Regulation title	Protections for Participants in Human Research
Date this document prepared	March 4, 2019

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations.*

Acronyms and Definitions

Please define all acronyms used in this Report. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

CFR = U.S. Code of Federal Regulations
DARS or the Department = Virginia Department for Aging and Rehabilitative Services
HRRC = Human Research Review Committee
IRB = Institutional Review Board
WWRC = Wilson Workforce and Rehabilitation Center

Legal Basis

Please identify (1) the agency or other promulgating entity, 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 entity to regulate this specific subject or program, as well as a reference to the agency or promulgating entity's overall regulatory authority.

Section 51.5-132 of the Code of Virginia directs the Commissioner to "promulgate regulations pursuant to the Administrative Process Act (§ 2.2-4000 et seq.) to effectuate the provisions of Chapter 5.1 (§ 32.1-162.16 et seq.) of Title 32.1 for human research, as defined in § 32.1-162.16, to be conducted or authorized by the Department, any sheltered workshop, any independent living center, or the Wilson Workforce and Rehabilitation Center." Further, § 51.5-132 requires the Department's regulations to "require the human research review committee, as provided in § 32.1-162.19, to submit to the Governor, the General Assembly, and the Commissioner or his designee, at least annually, a report on the human research projects reviewed and approved by the committee and shall require the committee to report any significant deviations from the proposals as approved."

34 CFR Part 97 and 45 CFR Part 46, specifically 34 CFR 97.101 and 45 CFR 46.101 respectively, requires that "all research involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency that takes appropriate administrative action to make the policy applicable to such research." Further, "institutions that are engaged in research… and institutional review boards (IRBs) reviewing research that is subject to this policy must comply with this policy."

Alternatives

Please 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 other alternatives to the proposed regulatory action; a periodic review of this regulation is required. The regulation prescribes research requirements for projects involving DARS or entities associated with DARS. There are no less intrusive or less costly alternatives.

Public Comment

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

DARS did not receive any public comments.

Effectiveness

Pursuant to § 2.2-4017, please indicate whether the regulation meets the criteria set out in Executive Order 14 (as amended, July 16, 2018), 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 regulation meets the criteria set out in Executive Order 14 (2018) as it is necessary for the protection of public health, safety and welfare of the citizens and visitors to the Commonwealth. The regulation protects the health and safety of participants in research by ensuring research projects are vetted appropriately, risks are minimized and participants are provided informed consent, when appropriate and required, and that records are sufficiently maintained. For researchers, the regulation has the beneficial impact of providing clear requirements and processes that also conform to federal requirements.

Decision

Please explain the basis for the rulemaking entity's decision (retain the regulation as is without making changes, amend the regulation, or repeal the regulation).

The agency recommends the regulation be amended to be achieve consistency with new federal requirements.

In 2017, sixteen federal departments and agencies, including the U.S. Departments of Health and Human Services, Education, Labor, and the Social Security Administration, issued final revisions to the "Federal Policy for the Protection of Human Subjects" (also known as "The Common Rule"). Per 82 FR 7149:

> "The departments and agencies listed in this document announce revisions to modernize, strengthen, and make more effective the Federal Policy for the Protection of Human Subjects that was originally promulgated as a Common Rule in 1991. This final rule is intended to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators. These revisions are an effort to modernize, simplify, and enhance the current system of oversight."

Following two delays in the effective date of the revised Common Rule (83 FR 2885 and 83 FR 28497), the final effective date was January 21, 2019.

As required by the Code of Virginia, the Department operates a Human Research Review Committee (HRRC; also frequently known as an IRB) and oversees research conducted by:

1. the Department;
2. Sheltered Workshops with vocational rehabilitation programs that have a vendor relationship with the Department and that are not community services boards;
3. Independent Living Centers; and
4. Wilson Workforce Rehabilitation Center (WWRC).

In order to maintain clarity and ensure consistency with updated federal requirements, the Department will seek to amend 22VAC30-40.

Small Business Impact

As required by § 2.2-4007.1 E and F of the Code of Virginia, include a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (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 the stated objectives of applicable law, will minimize the economic impact of regulations on small businesses.

There is a continued need for the regulations as they are mandated by law. No complaints or comments were received during the periodic review. The regulation supports clarity and ensures consistency with federal research requirements while further detailing the specific processes that DARS uses to review and oversee research. The regulation was last revised significantly in 2009. The only projected costs to affected entities, which may include small businesses, are any costs that may be related to completing the application to submit projects for review to the Department's HRRC. However, this cost is minimal and already exists with the current regulation.