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Exempt Action
Final Regulation
Agency Background Document

Agency name	Virginia Department for Aging and Rehabilitative Services
Virginia Administrative Code (VAC) citation(s)	22VAC30-40
Regulation title(s)	Protections of Participants in Human Research
Action title	Amend Human Research Regulations to Align with New Federal Requirements
Final agency action date	November 17, 2019
Date this document prepared	November 17, 2019

While a regulatory action may be exempt from executive branch review pursuant to § 2.2-4002 or § 2.2-4006 of the *Code of Virginia*, the agency is still encouraged to provide information to the public on the Regulatory Town Hall using this form. However, the agency may still be required to comply with the Virginia Register Act, Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations.*

Brief Summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

This regulation, 22VAC30-40, Protections of Participants in Human Research, specifies the criteria and processes for the Virginia Department for Aging and Rehabilitative Services (DARS) to evaluate research projects within DARS and for applicable covered entities, and to ensure research participants are protected and informed appropriately. Following a Periodic Review, the intent of this proposed regulatory action is to make changes to 22VAC30-40 to bring the existing regulation into conformity with recent changes to federal regulations (45 CFR Part 46, Protection of Human Subjects).

As required by the Code of Virginia, DARS operates a human research review committee (also known as an Institutional Review Board or IRB) and oversees research conducted by:

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

On average, DARS' Human Research Review Committee (HRRC) conducts about five to seven new reviews each year, with most filed as exempt or expedited. The HRRC also conducts about seven continued/ongoing reviews for existing projects, and closes out about three projects per year.

In order to maintain clarity and ensure consistency with updated federal requirements (see below), DARS seeks to amend 22VAC30-40. These changes will protect 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.

Mandate and Impetus

Please identify the mandate for this regulatory change, and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, internal staff review, petition for rulemaking, periodic review, board decision, etc.). "Mandate" is defined as "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

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 DARS, any sheltered workshop, any independent living center, or the Wilson Workforce and Rehabilitation Center." Section 51.5-132 further requires DARS' 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."

In 2017, sixteen federal departments and agencies, including the U.S. Departments of Health and Human Services, Education, and 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 Federal Register (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.

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

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

On November 17, 2019, DARS adopted the amendments to the Protections of Participants in Human Research (22VAC30-40).

Periodic Review
Small Business Impact Review Report of Findings

If you are using this form to report the result of a periodic review/small business impact review that is being conducted as part of this regulatory action, and was announced during the proposed stage, please indicate whether the regulatory change meets the criteria set out in Executive Order 14 (as amended, July 16, 2018), e.g., is necessary for the protection of public health, safety, and welfare; minimizes the economic impact on small businesses consistent with the stated objectives of applicable law; and is clearly written and easily understandable.

In addition, 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.

The agency received no public comments during the periodic review. The periodic review did reveal that changes were needed to the regulation to conform it to new federal requirements. The regulation meets the criteria of Executive Order 14 (as amended, July 16, 2018). It is necessary to protect the public health, safety and welfare of those individuals who participate in research. It minimizes the economic impact on small businesses consistent with the stated objectives of applicable law. The only projected costs to affected entities is the cost involved in completing the application requirements to submit proposed research for review to the Department's HRRC. However, this cost already exists with the current regulations. The regulation is clearly written and easily understandable.

The regulation has the beneficial impact of providing clear research requirements that conform to federal requirements and that protect individuals who participate in research. DARS has received no complaints or concerns related to this regulation. The regulation is straightforward and clear. The regulation aligns, but does not conflict, with federal requirements for research, and the need for the regulation is supported in the Code of Virginia (§ 51.5-132). The regulation was amended for minor changes in 2015 and 2012, and with substantial changes in 2005. With new federal regulations promulgated in 2017, the need to re-align the regulation prompted this change.