townhall.virginia.gov

Periodic Review and Small Business Impact Review Report of Findings

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) Chapter citation(s)	12VAC5-20
VAC Chapter title(s)	Regulations for the Conduct of Human Research
Date this document prepared	August 4, 2022

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.

VDH – Virginia Department of Health

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.

The State Board of Health is authorized to make, adopt, promulgate and enforce regulations by Section 32.1-12 of the Code of Virginia.

32.1-12.1 of the Code of Virginia requires the Board of Health to promulgate regulations for human research conducted or authorized by the Department or any facilities or other entities operated, funded, or licensed by the Department.

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.

No viable alternatives for achieving the purpose of the existing regulations could be determined. Section 32.1-12.1 of the Code of Virginia requires the Board of Health to promulgate regulations for human research conducted or authorized by the Department or any facilities or other entities operated, funded, or licensed by the Department.

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.

VDH did not receive any comments during the public comment period following the publication of the Notice of Periodic Review.

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 regulations meet the criteria set out in Executive Order 19 (2022) as they are necessary for the protection of public health, safety, and welfare of subjects in human subject research. The regulations are 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.

VDH is recommending the regulations be amended to reflect current practices based on the amended federal regulations for the Protection of Human Subjects (45 CFR 46).

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.

There is continued need for the regulations for the protection of subjects involved in human subject research in the Commonwealth of Virginia. These regulations establish the requirements for human subject research conducted or authorized by the Department of Health or any facilities or other entities operated, funded, or licensed by the Department. No public comments were received during the public comment period. The regulations are clearly written and easily understandable. The regulations do not conflict with any known federal or state law or regulation. Regulations are evaluated on an ongoing basis and these regulations were last amended in January 2016 as a result of periodic review. VDH does not anticipate that amending the regulations will have an adverse economic impact on small businesses in the Commonwealth of Virginia.