Form: TH-07 August 2022



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Periodic Review and Small Business Impact Review Report of Findings

Agency name	State Board of Education
Virginia Administrative Code (VAC) Chapter citation(s)	8 VAC20-565
VAC Chapter title(s)	Regulations for the Protection of Students as Participants in Human Research
Date this document prepared	September 26. 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.

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.

[&]quot;Board" means the Virginia Board of Education.

[&]quot;Department" means the Virginia Department of Education

The Board's overall regulatory authority is found in § 22.1-16 of the Code of Virginia, which states that "[t]he Board of Education may adopt bylaws for its own government and promulgate such regulations as may be necessary to carry out its powers and duties and the provisions of [Title 22.1 of the Code of Virginia]."

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The chapter further incorporates the requirements of § 32.162-16 et seq. of the Code of Virginia.

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 alternatives to this regulatory chapter were considered.

Public Comment

<u>Summarize</u> 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
none	none	none

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 regulatory chapter is necessary for the protection of public health, safety, and welfare. It is also clearly written and easily 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 regulation will 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.

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There is a continued need for the regulation. The VDOE did not receive any comments during the periodic review and is not aware of any complaints concerning the chapter. The regulation is not overly complex. The regulation overlaps § 32.162-16 et seq. of the Code of Virginia. The extent of any further overlap with federal or state laws and regulations is currently unknown. The regulation has not been amended since it was promulgated in 1995. The agency's decision is expected to have no impact on small businesses.