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Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Virginia Board of Education
Virginia Administrative Code (VAC) Chapter citation(s)	8 VAC 20-860 [new chapter]
VAC Chapter title(s)	Regulations Regarding Human Research
Action title	Establishing regulations regarding human research
Date this document prepared	October 18, 2021

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 (1VAC7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of the subject matter, intent, and goals of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation).

[Section 22.1-16.1](#) of the Code of Virginia requires the Virginia Board of Education (Board) “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 of Education [VDOE] or any public schools including the Virginia Schools for the Deaf and the Blind or any proprietary schools certified by the Board.” These regulations are intended to fulfill the Board’s statutory obligation.

Acronyms and Definitions

Define all acronyms or technical definitions used in this form.

Institutional Review Board (IRB): formal committee charged with protecting the rights and welfare of human subjects involved in research, including ensuring that all studies comply with the ethical principles contained in the Belmont Report, such as respect for people, beneficence and justice.

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, "mandate" has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), "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."

These regulations are being promulgated in order to fulfill a legislative mandate. [Section 22.1-16.1](#) of the Code of Virginia requires the Board "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 of Education or any public schools including the Virginia Schools for the Deaf and the Blind or any proprietary schools certified by the Board."

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 and 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 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 this title."

The Board's authority to promulgate regulations concerning human research is found in § [22.1-16.1](#) of the Code of Virginia. Section [22.1-16.1](#) requires the Board "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 of Education or any public schools including the Virginia Schools for the Deaf and the Blind or any proprietary schools certified by the Board."

Purpose

Describe the specific reasons why the agency has determined that this regulation is essential to protect the health, safety, or welfare of citizens. In addition, explain any potential issues that may need to be addressed as the regulation is developed.

The Board must promulgate regulations in order to comply with the legislative mandate in § [22.1-16.1](#) of the Code of Virginia.

Substance

Briefly identify and explain the new substantive provisions that are being considered, the substantive changes to existing sections that are being considered, or both.

The proposed regulations will 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 of Education or any public schools including the Virginia Schools for the Deaf and the Blind or any proprietary schools certified by the Board, as required by Section [22.1-16.1](#) of the Code of Virginia.

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulatory change.

There are no alternatives to regulation, as § [22.1-16.1](#) of the Code of Virginia explicitly directs the Board to promulgate regulations.

Periodic Review and Small Business Impact Review Announcement

If you wish to use this regulatory action to conduct, and this NOIRA to announce, a periodic review (pursuant to § 2.2-4017 of the Code of Virginia and Executive Order 14 (as amended, July 16, 2018)), and a small business impact review (§ 2.2-4007.1 of the Code of Virginia) of this regulation, keep the following text. Modify as necessary for your agency. Otherwise, delete the paragraph below and insert "This NOIRA is not being used to announce a periodic review or a small business impact review."

This NOIRA is not being used to announce a periodic review or a small business impact review.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below. In addition, as required by § 2.2-4007.02 of the Code of Virginia describe any other means that will be used to identify and notify interested parties and seek their input, such as regulatory advisory panels or general notices.

The agency is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal, (ii) any alternative approaches, and (iii) the potential impacts of the regulation.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at: <https://townhall.virginia.gov>. Comments may also be submitted to Alex Mattera by email to alex.mattera@doe.virginia.gov or by mail to the following address:

Alex Mattera
101 N. 14th St.
James Monroe Bldg
Richmond, VA 23219.

In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will not be held following the publication of the proposed stage of this regulatory action.