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Notice of Intended Regulatory Action (NOIRA) Agency Background Document

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| Agency name | Virginia Board of Education |
| Virginia Administrative Code (VAC) Chapter citation(s) | 8VAC20-565 |
| VAC Chapter title(s) | <i>Regulations for the Protection of Students as Participants in Human Research</i> |
| Action title | Action to review 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.”

Section 22.1-16.1 is currently implemented through the *Regulations for the Protection of Students as Participants in Human Research* (“the *Regulations*”; [8VAC20-565-10](#) et seq.). However, the *Regulations* do not contain sufficient detail to adequately implement the statutory requirement. The current action will amend the *Regulations* in order to provide more details for effectuating the requirements of Chapter 5.1 of Title 32.1 of the *Code of Virginia*.

Currently, the VDOE Office of Research requires evidence of Institutional Review Board (“IRB”) approval from an external organization—typically an accredited university—prior to obtaining access to restricted-use data for research. In addition, research studies that VDOE promotes or communicates to school divisions are required to demonstrate evidence of IRB approval. However, with a growing portfolio of research studies, VDOE would like to improve its process for reviewing research involving human subjects, which includes establishing an IRB. Moreover, an improved process would better align with the requirements of the Code of Virginia, which is for agencies conducting human research to establish an IRB.

By amending the *Regulations*, the Board will be able to offer VDOE and public schools better guidance as to how the provisions of Chapter 5.1 of Title 32.1 should be effectuated. The Board will engage a comprehensive review of the regulations in order to determine what changes should be made.

Acronyms and Definitions

Define all acronyms or technical definitions used in this form.

“Board” means the Virginia Board of Education.

“IRB” means an Institutional Review Board.

“The *Regulations*” means the *Regulations for the Protection of Students as Participants in Human Research* ([8VAC20-565-10](#) et seq.)

“VDOE” means the Virginia Department of Education.

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.”

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.”

Although the *Regulations* give some effect to the provisions of Chapter 5.1 of Title 32.1 for human research, a comprehensive review of the *Regulations* will allow the Board to provide more guidance.

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 current action is essential to protect the health, safety, and welfare of students in Virginia by setting clear guidance and expectations regarding the participation of students in human research. The *Regulations* ensure that human research unless the student or student’s parents have given their informed consent, that research is approved and conducted under the review of a human research committee, and that such research is conducted in accordance with applicable law.

The Board is not aware of any potential issues that may need to be addressed as the regulation is developed.

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 Board has determined that the *Regulations* do not contain sufficient detail and guidance in order to adequately effectuate Chapter 5.1 of Title 32.1 of the Code of Virginia. In order to provide more substantial guidance, the Board will need to amend the *Regulations*.

The Board intends to perform a comprehensive review of the *Regulations* and will consider substantive changes in the following areas:

- Additional definitions, including those definitions provided in § [32.1-162.16](#);
- A description of applicable statutory exemptions provided in § [32.1-162.17](#);
- Expanded definition regarding informed consent, pursuant to § [32.1-162.18](#);
- Policies regarding the composition and operation of the human research committee, including the provisions of § [32.1-162.19](#);
- Policies regarding the review and approval process of human research projects; and
- Policies regarding human research committee records and reporting.

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 a regulatory change. Section [22.1-16.1](#) of the Code of Virginia explicitly directs the Board to promulgate regulations in accordance with the Administrative Process Act.

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 action is being used to announce a periodic review pursuant to § [2.2-4017](#) of the *Code of Virginia*.

This action is not being used to announce small business impact review pursuant to § [2.2-4007.1](#) of the *Code of Virginia*.

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.

INSERT:

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, Floor
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.