|  |  |
| --- | --- |
| **Virginia Board of Education Agenda Item** | **Seal of the Commonwealth of Virginia** |

# Agenda Item: H

## Date: November 18, 2021

### Title: Final Review of Notice of Intended Regulatory Action to Develop Regulations for Human Research

#### Presenter: Dr. Jen Piver-Renna, Director of Research

#### Email: jennifer.piver-renna@doe.virginia.gov Phone: (804) 225-3698

## Purpose of Presentation:

Action required by state or federal law or regulation.

**Executive Summary:**
[Section 22.1-16.1](https://law.lis.virginia.gov/vacode/title22.1/chapter2/section22.1-16.1/) 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](https://law.lis.virginia.gov/vacodefull/title32.1/chapter5.1/) 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.

## Action Requested:

Final review: Action requested at this meeting

## Superintendent’s Recommendation: The Superintendent of Public Instruction recommends that the Board approve a Notice of Intended Regulatory Action (NOIRA) for to the development of regulations to establish an Institutional Review Board at VDOE

## Rationale for Action:

This action is required to align agency regulation with statutory requirement that all research involving human subjects be subject to review by an Institutional Review Board (IRB).

## Previous Review or Action:

No previous review or action.

**Background Information and Statutory Authority:**
The Board’s overall regulatory authority is found in [§ 22.1-16 of the *Code of Virginia*](https://law.lis.virginia.gov/vacode/title22.1/chapter2/section22.1-16.1/), 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](https://law.lis.virginia.gov/vacodefull/title32.1/chapter5.1/) 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.”

Section § 32.1-162.19 of the *Code of Virginia* reads, in part:

*Each institution or agency which conducts or which proposes to conduct or authorize human research shall establish a human research review committee. The committee shall be composed of representatives of varied backgrounds to ensure the competent, complete, and professional review of human research activities conducted or proposed to be conducted or authorized by the institution or agency. No member of the committee shall be directly involved in the proposed human research or have administrative approval authority over the proposed human research except in connection with his responsibilities as a member of the committee.*

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. However, with a growing portfolio of research studies, VDOE would like to improve their process for reviewing research involving human subjects, to include establishing an IRB.

**Timetable for Further Review/Action:**
Upon executive review and approval of the Notice of Intended Regulatory Action (NOIRA), VDOE will begin the development of proposed regulations for review by the Board.

## Impact on Fiscal and Human Resources:

The establishment and maintenance of a VDOE IRB will require additional capacity at the VDOE Office of Research. However, the fiscal and human resources impact cannot be estimated until proposed regulations are drafted.

# Attachment A

****

 townhall.virginia.gov

**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 |
| **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**

**[RIS1]**

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

[Section 22.1-16.1](https://law.lis.virginia.gov/vacode/title22.1/chapter2/section22.1-16.1/) of the Code of Virginia requires the Virginia Board of Education (Board) “to promulgate regulations pursuant to the Administrative Process Act (§ [2.2-4000](https://law.lis.virginia.gov/vacode/2.2-4000/) et seq.) to effectuate the provisions of Chapter 5.1 (§ [32.1-162.16](https://law.lis.virginia.gov/vacode/32.1-162.16/) et seq.) of Title 32.1 for human research, as defined in [§ 32.1-162.16](https://law.lis.virginia.gov/vacode/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.

**[RIS2]**
**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
[RIS3]**

*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](https://law.lis.virginia.gov/vacode/title22.1/chapter2/section22.1-16.1/) of the Code of Virginia requires the Board “to promulgate regulations pursuant to the Administrative Process Act (§ [2.2-4000](https://law.lis.virginia.gov/vacode/2.2-4000/) et seq.) to effectuate the provisions of Chapter 5.1 (§ [32.1-162.16](https://law.lis.virginia.gov/vacode/32.1-162.16/) et seq.) of Title 32.1 for human research, as defined in [§ 32.1-162.16](https://law.lis.virginia.gov/vacode/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.”

**[RIS4]
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](https://law.lis.virginia.gov/vacode/title22.1/chapter2/section22.1-16/) 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](https://law.lis.virginia.gov/vacode/title22.1/chapter2/section22.1-16.1/) of the Code of Virginia. Section [22.1-16.1](https://law.lis.virginia.gov/vacode/title22.1/chapter2/section22.1-16.1/) requires the Board “to promulgate regulations pursuant to the Administrative Process Act (§ [2.2-4000](https://law.lis.virginia.gov/vacode/2.2-4000/) et seq.) to effectuate the provisions of Chapter 5.1 (§ [32.1-162.16](https://law.lis.virginia.gov/vacode/32.1-162.16/) et seq.) of Title 32.1 for human research, as defined in § [32.1-162.16](https://law.lis.virginia.gov/vacode/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](https://law.lis.virginia.gov/vacode/title22.1/chapter2/section22.1-16.1/) 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](http://law.lis.virginia.gov/vacode/32.1-162.16/) et seq.) of Title 32.1 for human research, as defined in § [32.1-162.16](http://law.lis.virginia.gov/vacode/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](https://law.lis.virginia.gov/vacode/title22.1/chapter2/section22.1-16.1/) 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](https://law.lis.virginia.gov/vacode/title22.1/chapter2/section22.1-16.1/) of the Code of Virginia explicitly directs the Board to promulgate regulations.

**Periodic Review and**

**Small Business Impact Review Announcement**

**[RIS5]**

*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.

**[RIS6]
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, 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.