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Periodic Review and Small Business Impact Review Report of Findings

Agency name	Virginia Department of Corrections State Board of Local and Regional Jails
Virginia Administrative Code (VAC) Chapter citation(s)	__6__ VAC __15__ - __26__
VAC Chapter title(s)	Regulations for Human Subject Research
Date this document prepared	4/12/2022

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 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**.

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.

"Board" means State Board of Local and Regional Jails.

"Department" means the Department of Corrections.

"Director" means the Director of the Department of Corrections.

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.

These regulations are promulgated under the State Board of Local and Regional Jails (previously known as the Board of Corrections). Originally established under authority of §53.1-5.1 of the Code of Virginia, action by the 2020 Acts of the General Assembly (Chapter 759) repealed §53.1-5.1, divesting the Board of authority to promulgate these regulations. Therefore, the Board no longer has the authority to promulgate regulations regarding human subject research within the Department of Corrections and these regulations should be repealed under 6VAC 15. During the same legislative session, Chapter 759 added new language in §53.10 directing the Director of the Department to promulgate regulations for human research. New regulations will be promulgated under 6VAC 16 as appropriate.

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.

Due to changes in the Code of Virginia to §53.1-5.1 and §53.10 (Chapter 759, 2020 Acts of the General Assembly), the Board has no authority to issue these regulations. Therefore, they will be repealed under 6VAC 15. New regulations will be issued under 6VAC 16 as appropriate.

Public Comment

Summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and provide the agency 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.

No comments were received during the public comment period following the publication of the Notice of Periodic Review. No informal advisory group was formed for purposes of assisting in the periodic review.

Commenter	Comment	Agency response

Effectiveness

Pursuant to § 2.2-4017 of the Code of Virginia, indicate whether the regulation meets the criteria set out in Executive Order 14 (as amended, July 16, 2018), including why the regulation is (a) necessary for the protection of public health, safety, and welfare, and (b) is clearly written and easily understandable.

These regulations are not necessary under 6VAC 15. Due to changes in the Code of Virginia to §53.1-5.1 and §53.10 (Chapter 759, 2020 Acts of the General Assembly), the Board has no authority to issue these regulations. Therefore, they will be repealed under 6VAC 15.

However, these regulations are essential to safeguard human subject research and effectuate the provisions under Chapter 5.1 (§32.1-162.16 et seq.) of Title 32.1 for human research, as defined in §32.1-162.16. New regulations will be issued under 6VAC 16 as appropriate.

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).

Repeal the regulation under 6VAC 15.

On 3/16/2022, the Board voted unanimously to repeal this regulation. Due to changes in the Code of Virginia to §53.1-5.1 and §53.10 (Chapter 759, 2020 Acts of the General Assembly), the Board has no authority to issue these regulations. Therefore, they will be repealed under 6VAC 15.

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 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.

Due to changes in the Code of Virginia to §53.1-5.1 and §53.10 (Chapter 759, 2020 Acts of the General Assembly), the Board has no authority to issue these regulations. Therefore, they will be repealed under 6VAC 15. Repealing these regulations will have no negative impact on small businesses.
