



Virginia Department of Planning and Budget **Economic Impact Analysis**

6 VAC 16-20 Regulations for Human Subject Research
Department of Corrections
Town Hall Action/Stage: 6006 / 9697
August 30, 2022

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Code of Virginia (Code) and Executive Order 19. The analysis presented below represents DPB's best estimate of these economic impacts.¹

Summary of the Proposed Amendments to Regulation

Following a legislative change in the authority for this regulation, the Director of the Department of Corrections (DOC) proposes to establish rules governing human research, which are substantially the same as prior regulations, under a new Virginia Administrative Code (VAC) Chapter for DOC.

Background

This action would establish rules governing human research for DOC. Regulations regarding human research are for the protection of individuals participating in any sort of research which may expose such human subjects to physical or psychological injury as a consequence of participation as subjects, and which departs from the application of established and accepted therapeutic methods appropriate to meet the subjects' needs.

¹ Code § 2.2-4007.04 requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the analysis should include but not be limited to: (1) the projected number of businesses or other entities to whom the proposed regulatory action would apply, (2) the identity of any localities and types of businesses or other entities particularly affected, (3) the projected number of persons and employment positions to be affected, (4) the projected costs to affected businesses or entities to implement or comply with the regulation, and (5) the impact on the use and value of private property.

Chapter 759, 2020 Acts of Assembly, renamed the Board of Corrections as the State Board of Local and Regional Jails.² As a result, the location in Title 6 of the VAC where the Board of Corrections resided (6 VAC 15) was renamed for the State Board of Local and Regional Jails. This regulation currently exists under 6 VAC 15.

Chapter 759 also changed the authority for this regulation from the prior Board of Corrections to the Director of DOC. Hence, the Registrar assigned a new location for DOC regulations within Title 6 of the VAC (6 VAC 16). This action would establish substantially the same human research rules under the new Virginia Administrative Code 6 VAC 16 for DOC.³

Estimated Benefits and Costs

The prior rules for human research and the proposed new rules are substantially the same, except for adding the training requirement mandated by the federal Prison Rape Elimination Act (PREA) National Standards.⁴ According to DOC, the new regulation addresses PREA training which is required for all DOC personnel and its contractors, including entities authorized to conduct human research. DOC notes, however, that the training is free and takes limited time to complete. Furthermore, DOC is currently enforcing this training requirement as mandated by federal law (noted above). Thus, the primary effect of this action is to change the Virginia Administrative Code to reflect the statutory change in authority for this regulation and an existing requirement for PREA training under federal law. As a result, no economic impact is expected.

Businesses and Other Entities Affected

The regulations governing human subject research apply to any entity (private, public, nonprofit) which would propose research involving inmates, probationers, parolees, or other individuals under the supervision of DOC or its employees. DOC receives approximately eight proposals on average per year, and issues approximately three approvals which may include extensions of ongoing projects.

² <https://lis.virginia.gov/cgi-bin/legp604.exe?201+ful+CHAP0759>

³ This action does not repeal existing rules from the Virginia Administrative Code. According to DOC staff, the repeal will be done through a separate regulatory action.

⁴ Title 28, Chapter I, Part 115; 5 USC 301; 28 USC 509, 510; 42 USC 15601-15609.

The Code of Virginia requires DPB to assess whether an adverse impact may result from the proposed regulation.⁵ An adverse impact is indicated if there is any increase in net cost or reduction in net revenue for any entity, even if the benefits exceed the costs for all entities combined. As noted above, the proposed regulation is substantially the same as the prior regulation. Thus, no adverse impact is indicated on any entity.

Small Businesses⁶ Affected:⁷

The proposed regulation does not adversely affect small businesses.

Localities⁸ Affected⁹

The proposed regulation does not introduce costs for local governments.

Projected Impact on Employment

The proposed regulation does not affect total employment.

Effects on the Use and Value of Private Property

The proposed regulation does not affect the use and value of private property or the real estate development costs.

⁵ Pursuant to Code § 2.2-4007.04(D): In the event this economic impact analysis reveals that the proposed regulation would have an adverse economic impact on businesses or would impose a significant adverse economic impact on a locality, business, or entity particularly affected, the Department of Planning and Budget shall advise the Joint Commission on Administrative Rules, the House Committee on Appropriations, and the Senate Committee on Finance. Statute does not define “adverse impact,” state whether only Virginia entities should be considered, nor indicate whether an adverse impact results from regulatory requirements mandated by legislation.

⁶ Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as “a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.”

⁷ If the proposed regulatory action may have an adverse effect on small businesses, Code § 2.2-4007.04 requires that such economic impact analyses include: (1) an identification and estimate of the number of small businesses subject to the proposed regulation, (2) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the proposed regulation, including the type of professional skills necessary for preparing required reports and other documents, (3) a statement of the probable effect of the proposed regulation on affected small businesses, and (4) a description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation. Additionally, pursuant to Code § 2.2-4007.1, if there is a finding that a proposed regulation may have an adverse impact on small business, the Joint Commission on Administrative Rules shall be notified.

⁸ “Locality” can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulatory change are most likely to occur.

⁹ § 2.2-4007.04 defines “particularly affected” as bearing disproportionate material impact.