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## Fast-Track Regulation Agency Background Document

<b>Agency name</b>	Department of Corrections State Board of Local and Regional Jails
<b>Virginia Administrative Code (VAC) Chapter citation(s)</b>	__ 6 __ VAC 15 - 26 __
<b>VAC Chapter title(s)</b>	Human Subject Research
<b>Action title</b>	Repeal
<b>Date this document prepared</b>	8/24/2022 (Updated 12/7/2022)

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), 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 this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.*

The purpose of the proposed action is to repeal regulations regarding Human Subject Research under 6VAC15, the State Board of Local and Regional Jails. In 2020, Chapter 759 of the Acts of Assembly changed authority for these regulations from the prior Board of Corrections (under §53.1-5.1) to the Director of the Department of Corrections (under §53.1-10).

Due to changes in the Code of Virginia regarding regulatory authority for certain Department of Corrections responsibilities, a separate agency for regulations was established by the Virginia Registrar. In order to move these regulations from the agency number for the Board of Local and Regional Jails (6VAC15) to the agency number for the Department of Corrections (6VAC16), the regulations must be repealed under 6VAC15 and promulgated under 6VAC16.

For these reasons, the Fast Track process has been determined as the approach to ensure that the old regulations are repealed so the new regulations can be put in place under the correct agency and made available as soon as possible.

## Acronyms and Definitions

*Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.*

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

"Department" means the Department of Corrections.

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

## Statement of Final Agency Action

*Provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.*

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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, 6VAC15-26 Human Subject Research should be repealed.

## 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 the ORM procedures, "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."*

*Consistent with Virginia Code § 2.2-4012.1, also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track rulemaking process.*

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The purpose of this action is to repeal regulations regarding Human Subject Research under 6VAC15, the State Board of Local and Regional Jails. In 2020, Chapter 759 of the Acts of Assembly changed authority for these regulations from the prior Board of Corrections (under §53.1-5.1 of the Code of Virginia) to the Director of the Department of Corrections (under §53.1-10 of the Code of Virginia).

Specifically, the Code of Virginia directs the Director "[t]o promulgate regulations...for human research, as defined in §32.1-162.16, to be conducted or authorized by the Department. Therefore, the Board no longer has statutory authority to promulgate these regulations.

Due to the changes in the Code of Virginia regarding regulatory authority for certain Department of Corrections responsibilities, a separate agency for regulations was established in 2021 by the Virginia Registrar. In order to move these regulations from the agency number for the Board (6VAC15) to the newly established agency number for the Department of Corrections (6VAC16), the regulations must be

repealed under 6VAC15 and promulgated under 6VAC16. As there will be no substantive changes to the content of the regulations once they are moved to 6VAC16, the regulatory action will likely be non-controversial.

## 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 Virginia Department of Corrections is the promulgating agency. The State Board of Local and Regional Jails no longer has the authority to promulgate these regulations; therefore, they must be repealed.

In 2020, Chapter 759 of the Acts of Assembly changed authority for these regulations from the prior Board of Corrections (under §53.1-5.1 of the Code of Virginia) to the Director of the Department of Corrections (under §53.1-10 of the Code of Virginia).

## Purpose

*Explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it is intended to solve.*

- 1) These regulations are currently under the Board's regulatory authority (6VAC15), which has no authority to promulgate such regulations. Therefore, regulatory action is necessary to remove them from under the Board's authority.
- 2) As these regulations directly impact the health, safety, and welfare of citizens who may be subject to research projects, it is essential to their protection that the Virginia Administrative Code accurately reflects the appropriate promulgating authority.
- 3) The goal of this regulatory change is to move the regulations from under the Board's authority to the Virginia Department of Corrections' authority (6VAC16), which is the statutorily correct authority.

## Substance

*Briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of Changes" section below.*

This action is to repeal 6VAC15-26 in entirety so that the regulations may be promulgated under the appropriate agency (6VAC16-20).

## Issues

*Identify the issues associated with the regulatory change, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, include a specific statement to that effect.*

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Human subject research regulations are for the protection of a group of individuals who may be part of a research project. These projects are prevalent in agencies responsible for services and supervision, as well as universities. The regulations protect those involved in the research and provide those conducting the research with clarity and guidance.

Having these regulations under 6VAC15, with no regulatory authority for the Board to issues them, creates a problem for the public seeking to conduct research, and for the individuals who may be subject to such research. Separate regulatory action is necessary to place these regulations under 6VAC16 to ensure that they are in effect and in the appropriate regulatory authority.

The advantage of this regulatory change is that the Virginia Administrative Code will accurately reflect the appropriate promulgating authority. There are no disadvantages to this change.

**Requirements More Restrictive than Federal**

*Identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements, or no requirements that exceed applicable federal requirements, include a specific statement to that effect.*

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No requirements are noted as more restrictive than applicable federal requirements.

**Agencies, Localities, and Other Entities Particularly Affected**

*Consistent with § 2.2-4007.04 of the Code of Virginia, identify any other state agencies, localities, or other entities particularly affected by the regulatory change. Other entities could include local partners such as tribal governments, school boards, community services boards, and similar regional organizations. “Particularly affected” are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. “Locality” can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.*

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Other State Agencies Particularly Affected

No other state agencies will be affected.

Localities Particularly Affected

No localities will be affected.

Other Entities Particularly Affected

No other entities will be affected.

## Economic Impact

*Consistent with § 2.2-4007.04 of the Code of Virginia, identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Keep in mind that this is the proposed change versus the status quo.*

### Impact on State Agencies

<p><i>For your agency:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including:                  a) fund source / fund detail;                  b) delineation of one-time versus on-going expenditures; and                  c) whether any costs or revenue loss can be absorbed within existing resources</p>	<p>The proposed change from 6VAC15 to 6VAC16 and other un-substantial changes will have no increased costs or savings for other state agencies.</p>
<p><i>For other state agencies:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.</p>	<p>The proposed change from 6VAC15 to 6VAC16 and other un-substantial changes will have no increased costs or savings for other state agencies.</p>
<p><i>For all agencies:</i> Benefits the regulatory change is designed to produce.</p>	<p>The proposed change from 6VAC15 to 6VAC16 and other un-substantial changes will have no cost benefits for the Department or other agencies; however, the regulations will be appropriately placed and authority will not be questioned.</p>

### Impact on Localities

*If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a or 2) on which it was reported. Information provided on that form need not be repeated here.*

<p>Projected costs, savings, fees or revenues resulting from the regulatory change.</p>	<p>The proposed change from 6VAC15 to 6VAC16 and other un-substantial changes will have no increased costs for localities.</p>
<p>Benefits the regulatory change is designed to produce.</p>	<p>The proposed change from 6VAC15 to 6VAC16 and other un-substantial changes will have no increased cost benefits for localities.</p>

### Impact on Other Entities

*If this analysis has been reported on the ORM Economic Impact form, indicate the tables (1a, 3, or 4) on which it was reported. Information provided on that form need not be repeated here.*

<p>Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.</p>	<p>Private and nonprofit entities wishing to conduct research meeting the definition of human subject research are subject to the regulations. However, the primary change in the regulations is moving the location from 6VAC15 to 6VAC16 and the un-substantial changes will have no impact. These entities have been subject to the regulations under 6VAC15 historically.</p>
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<p>Agency's best estimate of the number of such entities that will be affected. Include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that:</p> <ul style="list-style-type: none"> <li>a) is independently owned and operated and;</li> <li>b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</li> </ul>	<p>The Department cannot estimate the number of entities or individuals that will be impacted by the regulations. Since the primary purpose is to change the location of the regulations from 6VAC15 to 6VAC16, and the changes included are not substantial, there is no perceived impact on such entities.</p>
<p>All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Be specific and include all costs including, but not limited to:</p> <ul style="list-style-type: none"> <li>a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses;</li> <li>b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change;</li> <li>c) fees;</li> <li>d) purchases of equipment or services; and</li> <li>e) time required to comply with the requirements.</li> </ul>	<p>This action is to repeal the regulations under 6VAC15; therefore no cost is associated with the action.</p>
<p>Benefits the regulatory change is designed to produce.</p>	<p>The proposal places these regulations under the proper regulatory agency, ensuring that the public finds the relevant regulations they may need to access.</p>

**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.*

This action is to repeal the existing regulations under 6VAC15, as the Board of Local and Regional Jails no longer has the authority issue these regulations. When the Virginia General Assembly changed authority for the regulations to the Director, enacting language did not allow for the transfer of regulations administratively, therefore, a formal regulatory process is necessary to ensure the regulations are repealed under 6VAC15 so that they may be placed under the proper agency, 6VAC16.

No additional costs or benefits will result from this action.

*If this analysis has been reported on the ORM Economic Impact form, indicate the tables on which it was reported. Information provided on that form need not be repeated here.*

**Regulatory Flexibility Analysis**

*Consistent with § 2.2-4007.1 B of the Code of Virginia, describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) establishing less stringent compliance or*

reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the regulatory change.

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As this action is to repeal the existing regulations in entirety so they may be placed under the appropriate agency.

*If this analysis has been reported on the ORM Economic Impact form, indicate the tables on which it was reported. Information provided on that form need not be repeated here.*

### 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.*

*Consistent with § 2.2-4011 of the Code of Virginia, if an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.*

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If you are objecting to the use of the fast-track process as the means of promulgating this regulation, please clearly indicate your objection in your comment. Please also indicate the nature of, and reason for, your objection to using this process.

The State Board of Local and Regional Jails is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal and any alternative approaches, (ii) the potential impacts of the regulation, and (iii) the agency's regulatory flexibility analysis stated in this background document.

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 by mail, email or fax to Colleen H. Maxwell, Board of Local and Regional Jails, Department of Corrections Headquarters, 6900 Atmore Drive, Richmond, Virginia, 23225; (804) 887-8445 (phone); (804) 674-3509 (fax); or [colleen.maxwell@vadoc.virginia.gov](mailto:colleen.maxwell@vadoc.virginia.gov). In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

### Detail of Changes

*List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.*

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If an existing VAC Chapter(s) is being amended or repealed, use Table 1 to describe the changes between existing VAC Chapter(s) and the proposed regulation. If existing VAC Chapter(s) or sections are being repealed and replaced, ensure Table 1 clearly shows both the current number and the new number for each repealed section and the replacement section.

**Table 1: Changes to Existing VAC Chapter(s)**

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
All chapters are being repealed			The Board of Local and Regional Jails no longer has the authority to issue these regulations. They are being repealed under 6VAC15 and promulgated in a separate regulatory action under 6VAC16.

If a new VAC Chapter(s) is being promulgated and is not replacing an existing Chapter(s), use Table 2.

**Table 2: Promulgating New VAC Chapter(s) without Repeal and Replace**

New chapter-section number	New requirements	Other regulations and law that apply	Intent and likely impact of new requirements

If the regulatory change is replacing an **emergency regulation**, and the proposed regulation is identical to the emergency regulation, complete Table 1 and/or Table 2, as described above.

If the regulatory change is replacing an **emergency regulation**, but changes have been made since the emergency regulation became effective, also complete Table 3 to describe the changes made since the emergency regulation.

**Table 3: Changes to the Emergency Regulation**

Emergency chapter-section number	New chapter-section number, if applicable	Current <u>emergency</u> requirement	Change, intent, rationale, and likely impact of new or changed requirements since emergency stage