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## Fast-Track Regulation Agency Background Document

<b>Agency name</b>	Department of Corrections
<b>Virginia Administrative Code (VAC) Chapter citation(s)</b>	__6__ VAC_16__-__20__
<b>VAC Chapter title(s)</b>	Human Subject Research
<b>Action title</b>	Reestablish Regulations Under 6VAC16
<b>Date this document prepared</b>	7/19/2022

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*.

### 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 this action is to establish regulations regarding Human Subject Research under 6VAC16, Department of Corrections. Currently, these regulations exist 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to the agency number for the Department of Corrections (6VAC16), the regulations must be promulgated under 6VAC16 and repealed under 6VAC15.

Prior to this action, a public comment period was initiated. No substantial changes have been made in the regulations beyond corrections to the regulatory authority, clarification in the prior use of "offenders", and

removal of an agency incorporated document (to comply with current regulatory guidance). A new training is required, however it is free and takes limited time to complete.

For these reasons, the Fast Track process has been determined as the approach to ensure that regulations are 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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The Director of the Department of Corrections approved promulgation of the Human Subject Research regulations under 6VAC16-20 on 6/6/2022.

### 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."*

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

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The purpose of this action is to establish regulations regarding Human Subject Research under 6VAC16, Department of Corrections. Currently, these regulations exist 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. The regulations shall require the human research committee to submit to the Governor, the General Assembly, and the Director or his designee at least annually a report on the human research projects reviewed and approved by the committee and shall require the committee to report any significant deviations from the proposals as approved". [§53.1-10(14)]

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 promulgated under 6VAC16 and repealed under 6VAC15.

Additionally, federal law and regulation require PREA training – Prison Rape Elimination Act National Standards (Title 28, Chapter I, Part 115; 5 USC 301; 28 USC 509, 510; 42 USC 15601-15609) - which has been added.

Prior to this action, a public comment period was initiated and no comments were received. No substantial changes have been made in the regulations beyond corrections to the regulatory authority, clarification in the prior use of “offenders”, and removal of an agency incorporated document (to comply with current regulatory guidance). The training has also been added and is free for anyone needing to take it.

For these reasons, the action is expected to be noncontroversial and the Fast Track process has been determined as the best approach to ensure that regulations are put in place under the correct agency and available for use as quickly as possible.

### 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.

Section 53.1-10 of the Code of Virginia specifies the following: “The Director shall be the chief executive officer of the Department and shall have the following duties and powers:...[t]o promulgate regulations...for human research, as defined in §32.1-162.16, to be conducted or authorized by the Department. The regulations shall require the human research committee to submit to the Governor, the General Assembly, and the Director or his designee at least annually a report on the human research projects reviewed and approved by the committee and shall require the committee to report any significant deviations from the proposals as approved”. [§53.1-10(14)]

The Code of Virginia is clear that regulations regarding human research are to be promulgated.

Federal requirements regarding PREA training - Prison Rape Elimination Act National Standards (Title 28, Chapter I, Part 115; 5 USC 301; 28 USC 509, 510; 42 USC 15601-15609).

### 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’s intended to solve.*

Regulations regarding human research exist 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.

These regulations are currently under the Board's regulatory agency number (6VAC15), which has no authority to promulgate such regulations. In order to move them under the Department's agency number (6VAC16), regulatory action is necessary.

## 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.*

The primary purpose of the change is to move the regulations from 6VAC15 (Board) to 6VAC16 (Department). Non-substantial changes to the regulations under 6VAC15 to those for 6VAC16 reflect:

- Removal of references to the Board of Corrections to comply with changes to the Code of Virginia
- A clarification of "offenders" which was used generically to be specific to "inmate, probationer, parolee or other individual under supervision of the Department of Corrections"
- Removal of internal documents unnecessarily incorporated by reference to comply with changes made to 1VAC7-10-140(D)
- Training need for compliance with the federal Prison Rape Elimination Act (training is free and takes limited time to complete)
- Updates to forms

## 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.*

Human subject research regulations are for the protection of a group of individuals who may be part of a research project. These 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.

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

## 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.*

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

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

*Identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "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.*

**Other State Agencies Particularly Affected**

The regulations governing human subject research impact any state agency which would propose research of inmates, probationers, paroles, or other individuals under the supervision of the Department, or Department employees. Primary agencies would be state universities or colleges. However, since the regulatory change is mostly a move from 6VAC15 to 6VAC16, with un-substantial changes, there is not expected to be any impact on other state agencies. PREA training, a new requirement, is free and takes limited time to complete.

**Localities Particularly Affected**

Localities are not expected to be impacted by the move from 6VAC15 to 6 VAC16, or any of the un-substantial changes, as localities generally do not engage in human subject research involving the Department, its employees, or its population.

**Other Entities Particularly Affected**

The regulations governing human subject research impact any private or nonprofit entity which would propose research of inmates, probationers, paroles, or other individuals under the supervision of the Department, or Department employees. However, since the regulatory change is mostly a move from 6VAC15 to 6VAC16, with un-substantial changes, there is not expected to be any impact on other entities. PREA training, a new requirement, is free and takes limited time to complete.

**Economic Impact**

*Pursuant to § 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 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;</p>	<p>The proposed change from 6VAC15 to 6VAC16 and other un-substantial changes will have no increased costs for the Department, as the Department already maintains and follows the</p>
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b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	regulations as originally promulgated under 6VAC15.
<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.	The proposed change from 6VAC15 to 6VAC16 and other un-substantial changes will have no increased costs or savings for other state agencies. PREA training is free and takes limited time.
<i>For all agencies:</i> Benefits the regulatory change is designed to produce.	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.

**Impact on Localities**

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

**Impact on Other Entities**

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.	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. The requirement for PREA training is of no cost to external entities and takes limited time.
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: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.	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 includes are not substantial, there is no perceived impact on such entities.
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: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change;	Although the proposal does add PREA training as a requirement, there is no significant cost associated with it. The Department provides the training and there is no cost to take it. It also takes limited time, so there is no substantial time required from affected individuals, businesses, or other entities.

c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	
Benefits the regulatory change is designed to produce.	The proposal places these regulations under the proper regulatory agency, ensuring that the public finds the relevant regulations they may need access to. Un-substantial changes clarify a generic term previously used (“offender”), removes inappropriate uses of documents incorporated by reference, and includes a training requirement that is for the protection of all parties.

**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.*

The Code of Virginia is specific that the Director is to promulgate regulations for human subject research. [§53.1-10(14)] As this is a directive of the Virginia General Assembly, there is no alternative to regulation.

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 under the proper agency (6VAC16).

**Regulatory Flexibility Analysis**

*Pursuant to § 2.2-4007.1B 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.*

The Department conducted an analysis of alternative regulatory methods consistent with health, safety, environmental, and economic welfare. The Department determined that establishing less stringent reporting requirements or deadlines would not be beneficial given that most such requirements or deadlines fall on the Department or its established committees, rather than on external parties. Researchers are required to report to the HRRC any noncompliance with the approved research proposal and to provide periodic progress reports. Striking these requirements would eliminate valuable information the department needs to determine whether these proposals should be terminated. To the extent this chapter impacts small businesses, exempting them from the requirements of these regulations would reduce uniformity and be counterproductive to the goal of establishing a clear process for all regulated entities.

**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.

As required by § 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.

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 Department of Corrections 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 Tracey L. Jenkins, Department of Corrections, 6900 Atmore Drive, Richmond, Virginia, 23225; (804) 887-7898 (phone); (804) 674-3509 (fax); or [Tracey.Jenkins@vadoc.virginia.gov](mailto:Tracey.Jenkins@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.

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

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
6VAC16-20-10	Definitions - identical to 6VAC15-26-10 other than: removal of "Board"; change in "Organizational work unit" to reflect existing Code; change in "Participant" to clarify application of regulation; removal of "incorporated by reference" to comply with current regulation guidance	NA	Moving the regulation from 6VAC15 to 6VAC16 ensures proper application and use; no fiscal changes or substantial changes to the entire regulation or the specific definitions
6VAC16-20-20	Applicability – identical to 6VAC15-26-20	NA	None – regulation in place, moving to proper agency number
6VAC16-20-30	Policy – Identical to 6VAC15-26-30 other than: clarifies participants (B, F, I); removes unnecessary incorporation by reference E	NA	None – regulation in place, moving to proper agency number; no substantial change
6VAC16-20-50	Composition – Identical to 6VAC15-26-50	NA	None – regulation in place, moving to proper agency number
6VAC16-20-60	Duties and responsibilities: Identical to 6VAC1526-61 other than: clarifies participants (2.c); adds requirement of PREA training	Federal law requires PREA training – Prison Rape Elimination Act National Standards (Title 28, Chapter I, Part 115; 5 USC 301; 28 USC 509, 510; 42 USC 15601-15609)	None – regulation in place, moving to proper agency number; addition of PREA training is provided free and takes limited time to complete
6VAC16-20-79	Reports – Identical to 6VAC15-26-71	NA	None – regulation in place, moving to proper agency number
6VAC16-20-80	Records maintenance – Identical to 6VAC15-26-81	NA	None – regulation in place, moving to proper agency number
6VAC16-20-90	Publication rights – Identical to 6VAC15-26-91	NA	None – regulation in place, moving to proper agency number
6VAC16-20-100	Research exempt from HSRRC review – Identical to 6VAC15-26-101 except for clarification of application in point 2 (there is not a separate Division of Education per se) and change of word agency to department in point 3 to conform to definitions used	NA	None – regulation in place, moving to proper agency number – edits have no substantial change

6VAC16-20-110	Waiver of signed voluntary informed consent form – Identical to 6VAC15-26-102	NA	None – regulation in place, moving to proper agency number
6VAC16-20-120	Role of the department and director – Identical to 6VAC15-26-120 other than removal of board references	NA	None – regulation in place, moving to proper agency number and removing references to board to comply with Code of Virginia
6VAC16-20-130	Applicability of state and federal policies	NA	None – regulation in place, moving to proper agency number and removing references to board and changing reference to Code of Virginia to comply with Code of Virginia

*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