



## Proposed Regulation Agency Background Document

<b>Agency name</b>	Department of Corrections
<b>Virginia Administrative Code (VAC) citation</b>	6VAC15-26
<b>Regulation title</b>	Regulations for Human Subject Research
<b>Action title</b>	Amend as necessary the 6VAC15-26, which establishes conditions, standards and procedures for review and approval of human subject research, on an informed consent basis, of offenders and employees of the Department of Corrections.
<b>Date this document prepared</b>	May 24, 2011

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Brief summary

6VAC15-26 governs the form and review process for research to be conducted on human subjects within the Department of Corrections. These regulations have been in place in their current form since 1994. Since that time, technologies and methodologies have evolved such that provision must be made for electronic transfer of information. The proposed amendments establish the Human Subject Research Review Committee and define the proposed research project information for the researcher to submit, the review process for approval, the agreements and conditions required for conducting an approved research project, the consent required from research subjects, the security of data collected, and the use of research findings

### Acronyms and Definitions

Amendments define "Human Subject Research Review Committee" or "HSRRC" as the Department of Corrections committee responsible for (i) reviewing all submitted research projects for completeness and compliance with the Regulations for Human Subject Research, with all applicable Department of Corrections operating procedures and with all applicable state and federal regulations pertaining to human subject research; (ii) approving or denying submitted research proposals; (iii) monitoring all approved research projects for adherence to the scope of the research that was approved; and (iv) reporting on all research projects approved, all research projects denied and the findings of all approved research projects. The composition of the HSRRC and its responsibilities shall be stated in Part II of this chapter.

**Legal basis**

Under the authority of §53.1-5.1 of the Code of Virginia, the Board of Corrections plans to amend these regulations pursuant to the APA , and under the provisions of Code of Virginia §32.1-162.16 et seq. for human research.

**Purpose**

6VAC15-26, Regulations for Human Subject Research, establish conditions, standards and procedures that facilitate the Department of Corrections' review and approval of human research, on an informed consent basis, of offenders and employees. These regulations apply to any individual group, or agency conducting research using human participants within the Virginia Department of Corrections, including any facility, program or organization owned, operated, funded, or licensed by the department.

**Substance**

6VAC15-26-10 Definitions: Definitions have been inserted or amended to address the amendments and additions of specific information within the regulation, including "Human Subject Research Review Committee" or "HSRRC", "Organizational work unit", "Research Agreement", "Research Proposal", and "Voluntary informed consent"

6VAC15-26-30 Policy: Adding and amending requirements that all participation in human subject research is voluntary, precautions will be exercised to avoid any known risk to participants, and that such research shall not be conducted without documentation of appropriate review and approval.

6VAC15-26-40 Certification process: Repealing Section

6VAC15-26-50 Composition: Amending to set the composition and functions of the HSRRC.

6VAC15-26-60 Elements of each committee's review process: Repealing Section; requirements incorporated into 6VAC15-26-61

6VAC15-26-61 Duties and Responsibilities: Adding section to set the duties and responsibilities of the HSRRC including requirements of 6VAC15-26-60

6VAC15-26-70 Kinds of research exempt from committee review: Repealing Section; requirements moved to 6VAC15-26-101

6VAC15-26-71 Reports: Adding section to require interim and final reports from the researcher to the HSRRC; reporting requirements previously in 6-VAC15-26-60

6VAC15-26-80 Expedited review procedures for certain kinds of research involving no more than minimal risk: Repealing section; no longer applicable.

6VAC15-26-81 Records Maintenance: Adding section requiring maintenance of certain records by the principal researcher

6VAC15-26-90 Informed consent: Repealing section; some requirements moved to 6VAC15-26-102, other requirements duplicate 6VAC15-26-30.

6VAC15-26-91 Publication Rights: Adding section setting the rights of the researcher, the HSRRC, and the Department of Corrections to access, use, and disseminate research findings.

6VAC15-26-100 Committee records: Repealing section; requirements moved to 6VAC15-26-61

6VAC15-26-101 Research Exempt From HSRRC Review: New section. Updates the requirements of 6VAC15-26-70

6VAC15-26-102 Waiver of Signed Voluntary Informed Consent form: New section. Setting the requirements and conditions signed informed consent forms are not needed

6VAC15-26-110 Mandatory reporting: Repealing Section

6VAC15-26-130 Applicability of state and federal policies: Moves exemption for research studies subject to federal regulation from 6VAC15-26-140.

6VAC15-26-140 Applicability of federal policies: Repealing Section; requirements moved to 6VAC15-26-130.

### Issues

This action poses no disadvantages to the public or the Commonwealth. The amendments affect internal operational practices, and serve to protect research subjects, the Department of Corrections and researchers. These regulations should prove advantageous by providing the opportunity to gather and develop knowledge to advance correctional and social sciences.

### Requirements more restrictive than federal

This action complies with federal requirements for ethical principles and guidelines for research involving human subjects.

### Localities particularly affected

There are no localities in Virginia that bear any identified disproportionate material impact that would not be experienced by other localities.

### Public participation

The agency is seeking comments on the intended regulatory action, including but not limited to 1) ideas to assist in the development of a proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit comments may do via the Regulatory Townhall website , [www.townhall.virginia.gov](http://www.townhall.virginia.gov) or by mail, email or fax to John Britton, Department of Corrections Research and Management Services, (804)674-3268 ext: 1241, FAX (804)674-3590, [john.britton@vadoc.virginia.gov](mailto:john.britton@vadoc.virginia.gov) . Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last day of the public comment period.

A public hearing will not be held.

**Economic impact**

*Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirements create the anticipated economic impact.*

<b>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source, and (b) a delineation of one-time versus on-going expenditures.</b>	There is no additional cost to implement the proposed regulations.
<b>Projected cost of the <i>new regulations or changes to existing regulations</i> on localities.</b>	There is no cost to localities.
<b>Description of the individuals, businesses or other entities likely to be affected by the <i>new regulations or changes to existing regulations</i>.</b>	The amendments to 6VAC15-26 principally affect internal operational practices and should have minimal impact on entities requesting to conduct human subject research in the Department of Corrections.
<b>Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected.</b> Small business means 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.	The Department of Corrections typically receives 15 to 20 research proposals per year almost all of which are from students or faculty associated with institutions of higher learning. There is no anticipated impact on small businesses.
<b>All projected costs of the <i>new regulations or changes to existing regulations</i> for affected individuals, businesses, or other entities. Please be specific and include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.</b>	There are no projected costs of the new regulations. The amendments to 6VAC15-26 principally affect internal operational practices and should minimal impact on entities requesting to conduct human subject research in the Department of Corrections. The provisions for electronic submission of research proposal documents results in reduction of printing, handling, and postage costs.
<b>Beneficial impact the regulation is designed to produce.</b>	The new regulations will streamline and standardize the process for submission and review of research proposals while ensuring the safety and security of research subjects and their information.

**Alternatives**

The board could not consider any alternative other than to amend these regulations for human subject research.

**Regulatory flexibility analysis**

This regulation does not directly affect services provided by small businesses; however the proposed review and agreement process between the DOC and research entities (i) provides such entities with

clear requirements, (ii) ensures consistency in review of research proposals, and (iii) ensures informed consent and the safety of research participants and security of data collected.

**Public comment**

No public comment was received during the NOIRA stage.

**Family impact**

The proposed amendments do not strengthen or erode the authority or rights of parents in education, nurturing and supervision of their children. There will be no impact on economic self-sufficiency, self pride, marital commitment or disposable family income.

**Detail of changes**

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, rationale, and consequences
6VAC15-26-10			Add "Human Subject Research Review Committee" or "HSRRC" Add "Organizational work unit" Add "Research Agreement" Add "Research Proposal" These additional definitions support changes to other sections of this action. Grammatical changes with no change in content. Amend "Voluntary Informed Consent" to prohibit waiver of rights. A copy of the Voluntary Informed Consent is incorporated by reference
6VAC15-26-20			Adds "Virginia" to define the Department of Corrections
6VAC15-26-30		Deletes: B. Each human research review activity shall be approved by a committee composed of representatives of varied backgrounds who shall assure the competent, complete and professional review of human research activities. C. research review committee D. The individuals conducting the research shall be required to notify all participants of research of the risks caused by the research which are discovered after the research has concluded. E. Department of Corrections	Adds: B. No offender shall be subjected to experimentation or participation in research against their will.  <u>C. HSRRC</u> D. Research involving known and substantive physical, mental or emotional risk to the participants, including the withholding of any prescribed program or treatment is specifically prohibited.  E. Medical research shall only be

		<p>studies, program evaluations, and routine data analyses for management purposes are exempt from this policy.</p> <p>F. The burden of proof for review by any committee shall be with the principal researcher.</p>	<p>conducted in accordance with Department of Corrections Operating Procedure 701.1 Health Services Administration, which is incorporated by reference with this chapter.</p> <p>F. Research shall not interfere with the rights of offenders or Department of Corrections employees.</p> <p>G. Proper precautions must be exercised for the protection of the research participants rights and for the overall safety and security of the public, the researcher and the Department of Corrections.</p> <p>H. Research shall not interfere significantly with ongoing programs or operations of the Department of Corrections.</p> <p>I. The research findings shall not identify individual participants. The confidentiality and anonymity of all offenders and other parties engaged in the research will be maintained.</p> <p>J. Researchers are required to notify all participants of risks caused by the research that are discovered after the research has concluded.</p> <p>K. Each human research activity shall be reviewed and approved by the HSRRC.</p> <p>L. No human research activity involving the Department of Corrections shall be initiated without a research proposal reviewed and approved by the HSRRC.</p> <p>M. Each submitted research proposal must be accompanied by a research agreement signed by the principal researcher, or research project supervisor or advisor.</p> <p>N. All research proposals, research agreements, and accompanying documentation must be submitted to the HSRRC electronically via e-mail.</p> <p>O. The burden of proof for review by the HSRRC shall be with the principal researcher</p> <p>P. Research shall not commence until all procedural and applicable human research reviews and approvals are completed and the Department of Corrections Director or applicable Deputy Director signs an approval memorandum on behalf of the Department. This approval memorandum and necessary information describing the project shall be sent to the appropriate Department of Corrections organizational unit head, regional director, and principal researcher.</p> <p>Q. This chapter does not apply to Department of Corrections studies, program evaluations, and routine data</p>
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			analyses for management purposes. Requirements do not change, these deletions and additions reorganize the chapter for more logical flow and facilitate replacing the "committee" with the HSRRC"
6VAC15-26-40		Certification Process	Section Repealed; requirements integrated into 6VAC15-26-30, 6VAC15-26-50, and 6VAC15-26-61
6VAC15-26-50		Title: Composition of research review committee	Changed to: Part II, Human Subject Research Review Committee (HSRRC), Composition. Amended to replace the research review committee with the HSRRC and update the member qualifications and duties.
6VAC15-26-60	6VAC15-26-61	Title: Elements of each committee's review process	Repeal 6VAC15-26-60, replace with 6VAC15-26-61 - Title: Duties and Responsibilities. Proscribes the research proposal review and recordkeeping responsibilities of the HSRCC.
6VAC15-26-70	6VAC15-26-101	Kinds of research exempt from committee review	Contents moved to new section to achieve more logical organization of the chapter.
6VAC15-26-80		Expedited review procedures for certain kinds of research involving no more than minimal risk	Section Repealed; No longer applicable.
6VAC15-26-90		Informed Consent	Section Repealed; Requirements incorporated into 6VAC15-26-30 and 6VAC15-26-102
6VAC15-26-100		Committee records	Section Repealed; Requirements moved to 6VAC15-26-61
6VAC15-26-110		Mandatory reporting	Section Repealed; Requirements incorporated into 6VAC15-26-61.
6VAC15-26-120		Role of the department, director and the board	Amends to allow a designee to fulfill the Director's responsibilities and replaces references to the organizational unit and committee with HSRRC.
6VAC15-26-130		Applicability of state policies	Title changed to Applicability of state and federal policies. Amends to include federal policy requirements from 6VAC15-26-140.
6VAC15-26-140		Applicability of federal policies	Sections Repealed; Requirements added to 6VAC15-26-130.

For new chapters, use this chart:

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
6VAC15-26-71	A. The principal researcher must submit progress reports to the HSRRC by the dates agreed upon in the research agreement. These progress reports must be submitted electronically via e-mail. B. The principal researcher	None	Sets the requirements for the principal researcher to report to the HSRRC and the DOC use of the final research report.

	<p>must submit a final report to the HSRRC. The final report must be submitted electronically via e-mail.</p> <p>C. The HSRRC reserves the right to reproduce the final report for official Department of Corrections use only.</p>		
6VAC15-26-81	<p>A. The principal researcher shall maintain records adequate to enable the Department of Corrections to ascertain the status of the research project at any given time.</p> <p>B. The principal researcher shall maintain completed Voluntary Informed Consent forms in a secure location for at least three years</p>	Records Retention and Disposition Schedules	Sets the record keeping requirements for the principal researcher.
6VAC15-26-91	<p>A. Researchers are not permitted to publish beyond the approved research proposal without further review and approval from the HSRRC.</p> <p>B. The researcher shall furnish the HSRRC with an electronic copy of the published research findings.</p> <p>C. The Department of Corrections shall be permitted to use the data collected in the research project and to reproduce the materials as they are published.</p> <p>D. Without the explicit written approval of the researcher, the Department of Corrections should not distribute any dissertation or thesis material that the researcher has not published or presented publicly or professionally.</p>	None	Sets the rights of the researcher and the DOC in the use and publication of research data and findings.
6VAC15-26-102	<p>A. The HSRRC may waive the requirement for the researcher to obtain a signed voluntary informed consent form for some or all participants in a research project if it finds that the only record linking the participant and the research</p>	<u>COV</u> §32.1-162.18	Sets the conditions whereby the requirement for voluntary informed consent may be waived.



	<p>would be the consent form and that the principal risk would be potentially harmful resulting from a breach of confidentiality.</p> <p>B. Each participant will be asked whether he or she wants documentation linking him or her to the research, and the participant's wishes will govern.</p> <p>C. In cases where the documentation requirement is waived, the HSRRC shall require the researcher to provide participants with a written statement explaining the research.</p>		
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