



## Final 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 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>	April 15, 2013

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

### Statement of final agency action

At its March 20, 2013 meeting, the Board of Corrections accepted the final amendments to 6VAC15-26, *Regulations for Human Subject Research*, and approved submission of the final regulation for public comment in accordance with the Virginia Administrative Process Act.

### 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, establishes 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.

**Changes made since the proposed stage**

Section number	Requirement at proposed stage	What has changed	Rationale for change
10	the Deputy Director of Administration	a Deputy Director	DOC Reorganization
10	withdraw his voluntary informed consent	withdraw his <u>or her</u> voluntary informed consent	Gender neutrality
30., P.	director or applicable deputy director	Department of Corrections Director or designee	DOC Reorganization
30., P.	regional director	Regional Operations Chief	DOC Reorganization
50	Composition of the HSRCC.	Composition	Redundant
50., A.	director	Department of Corrections Director	Clarification
61., B., 1., a., (7)	subdivision 1 a (1) of this subsection	principle researcher	Clarification
61., B., 2.	Compliance with this chapter, and all applicable state and federal laws and regulations.	Compliance with this chapter, all applicable Department of Corrections operating procedures, and all applicable state and federal laws and regulations.	Correct the omission
61., B., 3.	conduct of his staff	conduct of his <u>or her</u> staff	Gender neutrality
61., B., 3., e.	approval from the applicable Department of Corrections deputy director	approval from the Department of Corrections Director or designee	DOC Reorganization
61., F.	director or the appropriate deputy director	Department of Corrections Director or designee	DOC Reorganization
61., G.	director or the appropriate deputy director	Department of Corrections Director or designee	DOC Reorganization
61., G.	regional director	Regional Operations Chief	DOC Reorganization
61., H., 9.	the applicable deputy director, regional director	designee, Regional Operations Chief	DOC Reorganization

61., N.	director or his designee	Department of Corrections Director or designee	DOC Reorganization
91., E.	director or the appropriate deputy director	Department of Corrections Director or designee	DOC Reorganization
101., 4.	connot	cannot	Spelling Correction
120., A.	director or his designee	Department of Corrections Director or designee	DOC Reorganization
120., B.	director or his designee	Department of Corrections Director or designee	DOC Reorganization
130., B.	Annual certification shall be made that exempted projects have complied with the policies and regulations of federal agencies to the director and the board.	Annual certification shall be made to the Director and the Board of Corrections that exempted projects have complied with the policies and regulations of federal agencies.	Clarification

**Public comment**

Two comments were received; neither was relevant to the content of the proposed regulation.

**All changes made in this regulatory action**

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, and rationale
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	Adds: B. No offender shall be subjected to experimentation or participation in research against their will.

		<p>activities.</p> <p>C. research review committee</p> <p>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.</p> <p>E. Department of Corrections 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><u>C. HSRRC</u></p> <p>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.</p> <p>E. Medical research shall only be 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</p>
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			<p>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 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"</p>
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	<p>Changed to: Part II, Human Subject Research Review Committee (HSRRC), Composition.</p> <p>Amended to replace the research review committee with the HSRRC and update the member qualifications and duties.</p>
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.