



Final Regulation Agency Background Document

Agency name	Department (Board) of Juvenile Justice (Agency # 35)
Virginia Administrative Code (VAC) citation	6 VAC 35-170
Regulation title	MINIMUM STANDARDS FOR RESEARCH INVOLVING HUMAN SUBJECTS OR RECORDS OF THE DEPARTMENT OF JUVENILE JUSTICE
Action title	Establish a process for reviewing and approving research proposals involving human subjects, to effectuate the provisions of Chapter 5.1 (Section 32.1-162.16 et seq.) of Title 32.1 for human research.
Document preparation date	November 19, 2003

This information is required for executive review (www.townhall.state.va.us/dpbpages/apaintro.htm#execreview) and the Virginia Registrar of Regulations (legis.state.va.us/codecomm/register/regindex.htm), pursuant to the Virginia Administrative Process Act (www.townhall.state.va.us/dpbpages/dpb_apa.htm), Executive Orders 21 (2002) and 58 (1999) (www.governor.state.va.us/Press_Policy/Executive_Orders/EOHome.html), and the *Virginia Register Form, Style, and Procedure Manual* (http://legis.state.va.us/codecomm/register/download/styl8_95.rtf).

Brief summary

*Please provide a brief summary of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Do **not** state each provision or amendment or restate the purpose and intent of the regulation.*

The regulation establishes minimum standards for research on human subjects under the care of the Department of Juvenile Justice. It requires that the department establish a human research review committee, provides criteria for that committee to use in evaluating proposals involving human research, provides for informed consent by human subjects or their authorized representatives, establishes minimum requirements for researchers, and requires annual reports to the Governor, the General Assembly and the Board of Juvenile Justice on human research projects.

The regulation also establishes a process for reviewing and approving research on records and data of the department when human research is not involved.

Statement of final agency action

Please 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.

The Board of Juvenile Justice adopted MINIMUM STANDARDS FOR RESEARCH INVOLVING HUMAN SUBJECTS OR RECORDS OF THE DEPARTMENT OF JUVENILE JUSTICE as a FINAL regulation at its regularly scheduled meeting on November 12, 2003.

Legal basis

Please identify the state and/or federal source of legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly bill and chapter numbers, if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

If the final text differs from the text at the proposed stage, please indicate whether the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the final regulation and that it comports with applicable state and/or federal law.

Code of Virginia § 66-10.1 directs the Board of Juvenile Justice to promulgate regulations pursuant to the Administrative Process Act to effectuate the provisions of Chapter 5.1 (§ 32.1-162.16 et seq.) of Title 32.1 for human research to be conducted or authorized by the Department. Thus, the regulation is mandatory.

Code of Virginia § 66-10 (6) gives the Board of Juvenile Justice the power and the duty “to promulgate such regulations as may be necessary to carry out the provisions of this title and other laws of the Commonwealth administered by the Director of the Department.”

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The regulation is needed to protect the health, safety, confidentiality and informed consent rights of the subjects of human research, in accordance with Code of Virginia § 66-10.1 and Chapter 5.1 (§ 32.1-162.16 et seq.) of Title 32.1. Human research, by definition, may expose subjects to risk of harm. This regulation implements the protections outlined in statute to minimize those risks.

The goals of the new regulation are to provide a fair and thorough review of proposals to conduct human research, including review by a specially established human research review committee, periodic reports by researchers, and annual reports by the department to the Governor, the General Assembly and the Board of Juvenile Justice to ensure that human research is conducted with appropriate oversight.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

6 VAC 35-170-20 establishes general requirements of external researchers.

6 VAC 35-170-40 details the confidentiality requirements of all research, and requires that disclosures be in accordance with §16.1-300 of the Code of Virginia,

6 VAC 35-170-50 establishes the conditions for department approval of external research, which shall be determined in the department's sole discretion.

6 VAC 35-170-60 requires a formal research agreement signed by the director.

6 VAC 35-170-70 details requirements specific to human research. All human research shall comply with all applicable laws, particularly Chapter 5.1 (§ [32.1-162.16](#) et seq.) of Title 32.1 of the Code of Virginia. Research involving known and substantive risk to subjects, and all experimental medical, pharmaceutical or cosmetic research, are specifically prohibited. Incentives to participate in research are discouraged, but not prohibited.

6 VAC 35-170-80 reiterates the informed consent required for human research as set forth in Code of Virginia § 32.1-162.18.

6 VAC 35-35-90 identifies exemptions from the requirements governing human research, as set forth in Code of Virginia § 32.1-162.17. These activities may, however, be subject to the non-human research review and approval process established by the department.

6 VAC 35-170-100 sets out detailed requirements for the form and content of external research proposals.

6 VAC 35-170-110 describes the initial review by coordinator of external research.

6 VAC 35-170-120 establishes time frames for reviewing and approving research proposals that do not involve human research.

6 VAC 35-170-130 mandates creation of a Human Research Review Committee in accordance with § 32.1-162.19 of the Code of Virginia and sets parameters for its operation.

6 VAC 35-170-140 establishes the timeline for review of human research proposals, and provides for an expedited review when certain conditions are met.

6 VAC 35-170-150 establishes criteria to be used by the human research review committee in recommending approval of human research proposals.

6 VAC 35-170-160 addresses informed consent provisions. Modified consent procedures are permitted when specific conditions are met.

6 VAC 35-170-170 describes the options available to the human research committee in making a recommendation to the director; requires the director to act with 10 days; and requires that a signed Research Agreement be in place before the project may begin.

6 VAC 35-170-180 requires an annual review of hum research activities.

6 VAC 35-170-190 requites an annual report to the Governor, the General Assembly, and the director, in accordance with Code of Virginia § 66-10.1, and also to the Board of Juvenile Justice.

6 VAC 35-170-200 authorizes the department to require progress reports on any research project.

6 VAC 35-170-210 states that the department may use, as they are published, all data, summaries, charts, graphs or other illustrations resulting from the research project.

6 VAC 35-170-220 requires that a formal final report be submitted to the coordinator of external research, to include a disclaimer that the department does not necessarily endorse the research findings.

Issues

Please identify the issues associated with the proposed regulatory action, 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, please indicate.*

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- 1) The primary advantage to juveniles and their families is that their health, safety, confidentiality and informed consent rights will be protected by a formal process. The primary advantage to researchers is a fair, equitable process for evaluating research proposals and monitoring the progress of research under way.

- 2) The primary advantage to the department is having clear, consistent guidance on the factors to consider in approving research proposals.
- 3) There are no known disadvantages to the general public, to researchers, to human subjects, or to the department of juvenile justice.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar’s office, please put an asterisk next to any substantive changes.

No changes were made from the proposed text.

Section number	Requirement at proposed stage	What has changed	Rationale for change

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

No public comments were received following the publication of the proposed stage.

Commenter	Comment	Agency response

All changes made in this regulatory action

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail new provisions and/or all changes to existing sections.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
	6 VAC 35-170-10	NONE	Defines the terms used in the regulations.
	6 VAC 35-170-20	NONE	Establishes general requirements of external researchers. The principal researcher shall have academic or professional standing in the pertinent field or job-related experience in the areas of study or be directly supervised by such a person. Also, the principal researcher is responsible for the conduct of the research

			staff, the protection of the rights of subjects, and for providing the information required by the regulation or department policy.
	6 VAC 35-170-30	NONE	All research must conform to the standards of ethics of recognized professional associations.
	6 VAC 35-170-40	NONE	Details the confidentiality requirements of all research. Research findings shall not identify individual subjects, and any research-related information may be released only in accordance with §16.1-300 of the <u>Code of Virginia</u> ,
	6 VAC 35-170-50	NONE	Establishes the conditions for department approval of external research. The department must have sufficient financial resources and staff to support the research project; the benefits of the research must justify the department's involvement; the research must not interfere with department programs or operations and must be compatible with the purposes and goals of the juvenile justice system and with the department's organization.
	6 VAC 35-170-60	NONE	Requires a formal research agreement signed by the director.
	6 VAC 35-170-70	NONE	Details requirements specific to human research. All human research shall comply with all applicable laws, particularly Chapter 5.1 (§ <u>32.1-162.16</u> et seq.) of Title 32.1 of the <u>Code of Virginia</u> regarding human research. Research involving known and substantive physical, mental, or emotional risk to subjects, including the withholding of any prescribed program of treatment, and all experimental medical, pharmaceutical or cosmetic research, are specifically prohibited. Offering incentives to participate in research is discouraged, but not prohibited. Incentives must be appropriate to the juveniles' custodial status and proportionate to the situation.
	6 VAC 35-170-80	NONE	Riterates the informed consent required for human research as set forth in Code of Virginia § 32.1-162.18. Informed consent shall be given in writing by the subject or his legally authorized representative and witnessed. No person who is otherwise capable of giving informed consent shall be forced to participate in any human research. A legally authorized

			representative may not consent to non-therapeutic research unless the Human Research Review Committee determines that such non-therapeutic research will present no more than a minimal risk to the human subject. No informed consent form shall include any language through which the human subject waives or appears to waive any legal rights, including any release of any individual, institution, or agency or any agents thereof from liability for negligence.
	6 VAC 35-35-90	NONE	Identifies exemptions from the requirements governing human research, as set forth in Code of Virginia § 32.1-162.17. These activities may, however, be subject to the non-human research review and approval process established by the department.
	6 VAC 35-170-100	NONE	Sets out detailed requirements for the content of external research proposals, including information about the researcher and any funding sources, a description of the proposed research project and the specific purpose of the project with anticipated results; the research design and techniques for data collection and analysis; time frames; a listing of any resources the researcher will require from the department; endorsement from the head of the organizational unit where the research will be conducted; endorsement from a student researcher’s academic advisor; for research involving records of juveniles at state and local court service units, endorsement from the juvenile and domestic relations judge; for human research, endorsement from the institutional review board of the researcher’s institution or organization; and a signed and dated statement that the principal researcher and research staff have read, understand, and agree to abide by these regulations.
	6 VAC 35-170-110	NONE	Describes the initial review by coordinator of external research.
	6 VAC 35-170-120	NONE	Establishes time frames for reviewing and approving research proposals that do not involve human research.
	6 VAC 35-170-130	NONE	Mandates creation of a Human Research Review Committee in accordance with § 32.1-

			162.19 of the <u>Code of Virginia</u> and sets parameters for its operation.
	6 VAC 35-170-140	NONE	Establishes the timeline for review of human research proposals; allows an expedited review when the proposed research involves no more than minimal risk to the human subjects and certain other conditions are met.
	6 VAC 35-170-150	NONE	Establishes criteria to be used by the human research review committee in recommending approval of human research proposals. The committee shall recommend approval only when the methodology is adequate for the proposed research; the research, if non-therapeutic, presents no more than a minimal risk to the human subjects; the rights and welfare of the human subjects are adequately protected; appropriate provisions have been made to get informed consent from the human subjects; the researchers are appropriately qualified; the criteria and means for selecting human subjects are valid and equitable; and the research complies with the requirements of the regulation and applicable department policies.
	6 VAC 35-170-160	NONE	The human research review committee must review the research proposal's informed consent provisions. Modified consent procedures are permitted when specific conditions are met.
	6 VAC 35-170-170	NONE	Describes the options available to the human research committee in making a recommendation to the director. The director must act within 10 days. A signed Research Agreement must be in place before the project may begin.
	6 VAC 35-170-180	NONE	The human research committee must review human research activities annually to ensure that they are being conducted in conformance with the proposals as approved by the director.
	6 VAC 35-170-190	NONE	The human research committee must annually report to the Governor, the General Assembly, and the director, in accordance with Code of Virginia § 66-10.1, and submit the same report to the Board of Juvenile Justice.
	6 VAC 35-170-200	NONE	The department may require periodic reports on the progress of any research project.
	6 VAC 35-170-210	NONE	The research agreement must specify that the department has unrestricted permission to use,

			as they are published, all data, summaries, charts, graphs or other illustrations resulting from the research project.
	6 VAC 35-170-220	NONE	A formal final report must be submitted to the coordinator of external research. The report shall contain a statement that “The findings of this study are the responsibility of the researchers, and cooperation by the Virginia Department of Juvenile Justice in facilitating this research should not be construed as an endorsement of the conclusions drawn by the researchers.”

Impact on family

Please assess the impact of the proposed regulatory action on the institution of the family and family stability.

The informed consent provisions of the regulation ensure that parents of minors who may be the subject of human research are involved in the decision to have their child participate in the research project. Otherwise, apart from protecting the confidentiality of research subjects and their families, the regulation does not have any particular impact on the institution of the family and family stability. The regulation neither encourages nor discourages economic self-sufficiency, self-pride, or the assumption of responsibility for oneself, one’s spouse or one’s children or elderly parents. The regulation does not strengthen or erode the marital commitment and neither increases nor decreases disposable family income.