Virginia Regulatory Town Hall

Proposed Regulation
Agency Background Document

Agency Name:	Department (Board) of Juvenile Justice (Agency # 35)
VAC Chapter Number:	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.
Date:	April 10, 2003

This information is required pursuant to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99), and the *Virginia Register Form,Style and Procedure Manual*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

Summary

Please provide a brief summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed. There is no need to state each provision or amendment or restate the purpose and intent of the regulation; instead give a summary of the regulatory action and alert the reader to all substantive matters or changes. If applicable, generally describe the existing 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.

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority must be provided. Please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed 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 provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the proposed regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of 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. Please note that a more detailed discussion is required under the statement providing detail of the regulatory action's changes.

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 provide a statement identifying the issues associated with the proposed regulatory action. The term "issues" means: 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 include a sentence to that effect.

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

Fiscal Impact

Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget

activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; and e) the projected cost of the regulation for affected individuals, businesses, or other entities.

There will be no cost to the state to implement the proposed regulation. As a matter of practice, the department has in place a process for receiving, evaluating and approving research proposals. The regulation merely standardizes and formalizes the process. There is no projected cost to localities to implement the proposed regulation. The regulation will most directly affect academic and social science researchers, and the individuals who are the subjects of human research. Any research inherently involves costs of time and resources, and the added costs to the researcher to comply with the regulation would be marginal. These added costs would include the time required to consult with the head of the organizational unit where the research would take place (if applicable), and the cost of progress reports and final reports required by the department. In recent years, the department has received fewer than a dozen formal research proposals each year. There is no reason to expect the volume of proposals to increase or decrease due to the adoption of this regulation.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or cross-walk - of changes implemented by the proposed regulatory action. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes.

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6 VAC 35-170-10 defines the terms used in the regulations.

6 VAC 35-170-20 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 requires that all research conform to the standards of ethics of recognized professional associations.

6 VAC 35-170-40 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 Code of Virginia,

6 VAC 35-170-50 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 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 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 reiterates 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 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 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 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 the proposed research involves no more than minimal risk to the human subjects and certain other 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. 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 requires the human research review committee to review the research proposal's 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 the human research committee to 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 requites the human research committee annually to report to the Governor, the General Assembly, and the director, in accordance with Code of Virginia § 66-10.1, and to submit the same report to the Board of Juvenile Justice.

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

6 VAC 35-170-210 states that the research agreement shall 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 requires that a formal final report 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."

Alternatives

Please describe the specific alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.

The department is currently operating under agency policies and procedures that establish essentially the same requirements as are set forth in the regulation. However, the Code of Virginia is clear that human research must be approved and conducted in conformity with regulations that are adopted pursuant to the Administrative Process Act, so the continued use of agency policy and procedure as guidance governing human research is not an acceptable alternative to the regulation.

Public Comment

Please summarize all public comment received during the NOIRA comment period and provide the agency response.

No comments were received from the general public nor from researchers. Department staff suggested minor language changes, and recommended that the regulation include the exact language required in the disclaimer to be included in the researcher's final report. This recommendation, along with the minor language changes, have been incorporated into the proposed regulation.

Clarity of the Regulation

Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

Based on review by department personnel who oversee the current procedures for reviewing and approving research proposals, the regulation is clearly written and easily understandable by the individuals who would be submitting formal proposals for human research or research on information and data of the department of juvenile justice.

Periodic Review

Please supply a schedule setting forth when the agency will initiate a review and re-evaluation to determine if the regulation should be continued, amended, or terminated. The specific and measurable regulatory goals should be outlined with this schedule. The review shall take place no later than three years after the proposed regulation is expected to be effective.

Three years after the effective date of this regulation, the department will initiate a review to determine if the regulation should be continued, amended or terminated. The review will determine whether the following goals have been met and continue to be met:

1. that the regulation implement the statutory requirements for human research and the statutory protections for human research subjects. If the Code of Virginia has been changed since the adoption of the regulation, the regulation will be updated.
2. that the review and approval of research proposals be conducted expeditiously and fairly. If the process results in delays or in complaints about uneven treatment, the regulation will be revised to correct the problems.
3. that the health, safety and confidentiality of human research subjects be protected.
4. that research projects enhance and support, or at least do not infringe upon, operations of the department.

Family Impact Statement

Please provide an analysis of the proposed regulatory action that assesses the potential impact on the institution of the family and family stability including the extent to which the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

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.