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## Final Regulation Agency Background Document

<b>Agency name</b>	Department (Board) of Juvenile Justice
<b>Virginia Administrative Code (VAC) citation(s)</b>	6 VAC 35-170
<b>Regulation title(s)</b>	MINIMUM STANDARDS FOR RESEARCH INVOLVING HUMAN SUBJECTS OR RECORDS OF THE DEPARTMENT OF JUVENILE JUSTICE
<b>Action title</b>	To provide for a comprehensive review of the process for reviewing and approving data requests and research proposals involving human subjects, to effectuate the provisions of Chapter 5.1 (Section 32.1-162.16 <i>et seq.</i> ) of Title 32.1 for human research
<b>Date this document prepared</b>	July 18, 2016

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.*

The proposed language describes how all external data requests and research proposals within the Commonwealth's juvenile justice system will be coordinated, reviewed, and approved or denied. The proposed language provides the process for the review and approval of two types of external data requests and a human research proposal. These include: 1) external aggregate data requests, 2) external case-specific data requests, and 3) human research proposals. The regulation as drafted addresses the process for the review and consideration of research proposals involving human research and provides basic guidance for research proposals or data requests that do not involve human research. Additional

language has been proposed to address researchers who fail to comply with the requirements of approved proposals.

### Acronyms and Definitions

*Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the “Definition” section of the regulations.*

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Board – State Board of Juvenile Justice  
Department – Department of Juvenile Justice

### 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.*

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On June 15, 2016, the Board of Juvenile Justice authorized the advancement of the Minimum Standards for Research Involving Human Subjects or Records of the Department of Juvenile Justice regulation, 6VAC35-170, as amended, to the Final Stage of the regulatory process.

### Legal basis

*Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person’s overall regulatory authority.*

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Section 66-10.1 of the *Code of Virginia* requires the State Board of Juvenile Justice (Board) 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. The Board is empowered with general authority to promulgate regulations pursuant to § 66-10 of the *Code of Virginia*, which authorizes the Board to “promulgate such regulations as may be necessary to carry out the provisions of this title and other laws of the Commonwealth.”

### Purpose

*Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation 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.*

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The *Minimum Standards for Research Involving Human Subjects or Records of the Department of Juvenile Justice* (6VAC35-170) establish the regulatory requirements for research on human subjects

who are under the care or supervision of Department or other Board-regulated programs or facilities. The regulation became effective February 1, 2005, and is intended to protect the safety, rights, and confidentiality of human research subjects.

The Board approved the submission of a Notice of Intended Regulatory Action (NOIRA) for 6VAC35-170, *Minimum Standards for Research Involving Human Subjects or Records of the Department of Juvenile Justice*, on September 13, 2013; and it was submitted on February 18, 2014. The Executive Branch review for this stage was completed on March 13, 2014. The NOIRA was published in the *Virginia Register of Regulations* on April 21, 2014. The public comment period ended on May 21, 2014. The Board approved the amendments to the regulatory language on November 12, 2014, and the proposed language was published in the *Virginia Register of Regulations* as part of the Proposed Regulatory Stage on December 28, 2015. The public comment period for the Proposed Regulatory Stage ended on February 28, 2016. No public comments were received during the comment period. The Department recommended two additional amendments to the proposed language. The Board approved the submission of the proposed regulation, as amended, to the Final Stage of the Regulatory Process for Executive Branch review on June 15, 2016.

## Substance

*Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both.*

The proposed language describes how all external data requests and research proposals within the Commonwealth's juvenile justice system will be coordinated, reviewed, and approved or denied. Specifically, the proposed language sets out the process for the review and approval of two types of external data requests: 1) external aggregate data requests (New Section: 6VAC35-170-62) and 2) external case-specific data requests (New Section: 6VAC 35-170-65). Proposed language also addresses researcher noncompliance (New Section: 6VAC35-170-185). Additional revisions have been proposed to bring the current language in the regulation related to human research in line with the requirements of Title 32.1 of the *Code of Virginia*.

## 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.*

The primary advantage of the proposed amendments to the public is that the requirements and decision process for research proposals that do not involve human research are clear in the regulation. Additionally, language has been proposed requiring a layer of review to ensure juvenile information is adequately protected when providing de-identified data. The current timeline for the decision process for research proposals not involving human research is 40 days. The proposed timeline for the decision process for aggregate data requests has been shortened to 20 days. The primary advantage to the Department and the Commonwealth is proposed language allowing the Department the discretion to approve or deny research projects to ensure selected projects align with the current Department needs

and priorities. Finally, proposed language allows the Department or the Human Research Review Committee to restrict or terminate the work of researchers who fail to comply with the approved conditions of a research proposal. There are no disadvantages to the public, the Department, or the Commonwealth in adopting the proposed changes to the regulation.

### Requirements more restrictive than federal

*Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include 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 statement to that effect.*

Section 66-10.1 of the *Code of Virginia* directs the Board 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. Per the requirements of 32.1-162.19, all institutions or agencies proposing to conduct or conducting human research shall establish a human research review committee. The requirement to establish a human research review committee adds an additional step to the human research proposal decision process, which makes the current regulations more restrictive than the federal requirements. Title 45 of the *Code of Federal Regulations* requires that for any research proposals conducted or supported by a federal agency, the institution must establish an institutional review board (IRB) to review research proposals, determine if the research meets the federal requirements, and approve or deny the proposal. Juvenile justice related human research proposals conducted by or sponsored by universities and university students are reviewed through the university's IRB and the Department's Human Research Review Committee. The additional step in the decision process is statutorily required and is intended to protect the safety, rights, and confidentiality of human subjects under the care or supervision of Department or other Board-regulated programs or facilities.

### Localities particularly affected

*Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.*

No localities will be particularly affected if 6VAC35-170 is amended.

### Family impact

*Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent 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 regulation is not anticipated to have a direct impact, either positively or negatively, on the institution of the family and family stability. The regulation does include provisions for parents to be involved in

giving informed consent to human research involving a minor. The regulation allows parents to maintain their authority and rights in determining whether their children participate in human research. The regulation neither encourages nor discourages economic self-sufficiency, self-pride, and the assumption of responsibility. The regulation neither strengthens nor erodes marital commitment, nor does it increase or decrease disposable family income.

### Changes made since the proposed stage

*Please list all changes that made to the text of the proposed regulation and the rationale for the changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. \*Please put an asterisk next to any substantive changes.*

Section number	Requirement at proposed stage	What has changed	Rationale for change
6VAC35-170-62	The proposed language to the regulation would have required the coordinator of external research to make certain specified determinations regarding the feasibility of granting an aggregate data request prior to approving the request. Additionally, the proposed language would have given the coordinator of external research the discretion to approve and coordinate the provision of data in response to the aggregate data request.	References to the “coordinator of external research” in Section 62 have been replaced with “the department.” As a result, the Department will be required to make the specified determinations regarding the feasibility of granting an aggregate data request prior to approving the request; and the Department will have the discretion to approve and coordinate the provision of data in response to the data request. The amendment gives the Department discretion as to which individual within the Department makes these decisions.	This change is necessary to give the Department the discretion in this process to determine the staff or representative that will be responsible for carrying out these requirements.

### 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. Please distinguish between comments received on Town Hall versus those made in a public hearing or submitted directly to the agency or board.*

No public comments were submitted.

**All changes made in this regulatory action**

*Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections. Explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation*

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
N/A	N/A	Identifies as the title of the regulation: Minimum Standards for Research Involving Human Subjects or Records of the Department of Juvenile Justice	<p>Amends the title of the regulation to: Regulation Governing Minimum Standards for Juvenile Information Requests from and Research Involving Human Subjects within the Department of Juvenile Justice.</p> <p>The new title rearranges requests for juvenile information and human research requests in order to remain consistent with the sequence of the proposed language in the regulation.</p>
6VAC35-170-10	N/A	Defines the terms that are used within the regulation.	<p>The following terms and definitions are added to ensure the public understands the meaning of terms used throughout the regulation:</p> <ul style="list-style-type: none"> <li>• “Aggregate data” means statistics that relate to broad classes, groups, or categories so that it is not possible to distinguish the properties of individuals within those classes, groups or categories.</li> <li>• “Case-specific data” means nonaggregated data that provides information about individuals within a group.</li> <li>• “De-identified data” means data with common identifiers, such as names, phone numbers, social security numbers, addresses, etc. removed in order to eliminate the ability of an individual viewing the data to determine the identity of an individual.</li> <li>• “Encrypted” means the transformation of data through the use of an algorithmic process into a form in which there is a low probability of assigning meaning without the use of a confidential process or key or the securing of the information by another method that renders the data elements unreadable or unusable.</li> <li>• “External research” means research conducted at or using the resources of a</li> </ul>

			<p>facility, program, or organization that is owned, operated, or regulated by the Department or the Board of Juvenile Justice by researchers who are not part of the department or under contract to the department, or who are not employees of another state agency conducting a study at the direction of the General Assembly.</p> <ul style="list-style-type: none"> <li>• “Human research review committee” means the committee established by the department to oversee human research proposals and activities in accordance with 6VAC35-170-130 and § 32.1-162.19 of the <i>Code of Virginia</i>.</li> <li>• “Human subject” means any individual who is under the department’s care, custody, or supervision, or a member of the facility of such an individual, who is, or who is proposed to be, a subject of human research.</li> <li>• “Written” means the required information is communicated in writing. Such writing may be available in either hard copy or electronic form.</li> </ul> <p>The definition of “human research” was amended to be consistent with the definition in § 32.1-162.19 of the <i>Code of Virginia</i>.</p> <p>The definition of “organizational unit head” was amended to remove references to “halfway houses” and “regional offices.” Currently, the Department does not operate halfway houses. “Regional offices” are covered by the reference to “court service units.”</p>
6VAC35-170-30	N/A	Currently, research must conform to the ethical standards of professional societies, such as the American Correctional Association, the American Psychological Association, the American Sociological Association, the National Association of Social Workers, or their equivalent.	Adds the American Evaluation Association to the list of professional societies that follow the standard of ethics to which all research must conform. This revision was made to address the evaluation component that most research proposals possess.
6VAC35-170-40	N/A	Although records of information given by research subjects or employees of the department must be kept confidential, confidentiality	Removes excess verbiage in the regulation and replaces language with a term that has been defined in the regulation. The new language reads: “Confidentiality does not preclude reporting results utilizing de-identified data or giving raw data to the

		does not preclude reporting results <i>in a consolidated form that protects the identity of individuals.</i>	department for possible further analysis.”
6VAC35-170-50	N/A	Projects meeting the listed conditions are required to be approved.	<p>The language in this section has been changed from “will” to “may.” The term “will” implies the project must be approved if all conditions are met. The term “may” allows the Department to deny approval for other reasons (e.g., the research is compatible with overall goals but may not address current Department priorities).</p> <p>Adds language to clarify that a proposal may only be approved if the conditions are met.</p> <p>Adds language requiring the data requests to comply with all Department procedures, which must be posted on the Department’s website.</p>
N/A	6VAC 35-170-62	N/A	<p>Adds language describing the process for reviewing and determining approval or denying approval for a request for aggregate data.</p> <p>Aggregate data requests must be submitted to the Department according to procedures posted on the Department’s website. Aggregate data requests meeting regulatory and Department procedural requirements will be reviewed and approved or denied within 20 business days of the Department’s receipt of the proposal. The Department must provide the researcher with the rationale for any denied requests and a written timeline for receipt of the data, when applicable. The proposed section allows aggregate data requests to be reviewed and processed in a timely manner by the Department.</p>
N/A	6VAC35-170-65	N/A	<p>Adds language describing the process for reviewing and determining approval or denying approval for a request for external case-specific data.</p> <p>Requires a committee designated by the Director to:</p> <ul style="list-style-type: none"> <li>• Review the data requested and determine if it is necessary to restrict the scope of the information provided. The scope of information may be restricted for any reason.</li> <li>• Determine the research is beneficial to the Department.</li> <li>• Ensure juvenile confidential information will be adequately</li> </ul>

			<p>protected.</p> <ul style="list-style-type: none"> <li>• Make a recommendation to the Director or his designee to approve or disapprove the request.</li> </ul> <p>Lists identifiers to be removed prior to sending data to a researcher. Permits the Director or his designee, on a case-by-case basis, to approve the dissemination of data containing a limited number of otherwise excluded identifiers for research benefiting the Department. Requires juvenile record information provided to the researcher to be encrypted.</p> <p>The proposed section allows de-identified data requests to be reviewed and processed in a timely manner and makes the public aware of the process.</p>
6VAC35-170-80	N/A	Requires written, informed consent be given by the subject, if competent, and by the authorized legal representative if not competent or if a minor.	Adds a requirement that, in the case of two or more individuals who are able to provide consent, both individuals must consent to the subject's participation in human research. This language is needed to make the section more consistent with informed consent requirements stated in § 32.1-162.18 of the <i>Code of Virginia</i> .
6VAC35-170-100	N/A	Endorsements are required for external research proposals, but there is no requirement that the endorsement be in writing.	Adds language requiring endorsements from the heads of organizational units, juvenile and domestic relations judges, and institutional review boards to be in writing.
6VAC35-170-120	N/A	Requires departmental staff to review research proposals not involving human research and make a recommendation to the director within 20 days of receipt, who then has 10 days to approve or deny the proposal.	Repeals section as unnecessary because the proposed sections on aggregate data requests (6VAC35-170-62) and case-specific de-identified data requests (6VAC35-170-65) address research proposals not involving human research.
6VAC35-170-140	N/A	Requires the human research review committee to review proposals within 30 days of receiving the completed proposals.	Clarifies that the 30-day review requirement denotes 30 business days.
6VAC35-170-170	N/A	Requires the Director to approve or deny the human research proposal within 10 days of receiving the committee's recommendation.	Clarifies that the 10-day notification requirement denotes 10 business days.
N/A	6VAC35-170-185	N/A	Adds language requiring the researcher to report noncompliance to the Human Research Review Committee and the institutional review board. Adds language to outline the consequences

			for a researcher's failure to comply with the approved proposal, state statutes, or regulations governing external research.
6VAC35-170-190	N/A	Requires the Human Research Review Committee to annually submit to the Board of Juvenile Justice a report on human research projects approved by the committee, a summary of human research proposals not approved by the committee, and the status of the research.	Removes the requirement that the committee submit to the Board a summary of human research proposals that were not approved.  The Department receives requests for data and partnering to conduct research by phone, email, letter, and in person. Department procedure requires that the individual complete the appropriate forms when requesting data. Additionally, initial requests for data are made and when additional information is required of the researcher, there are cases in which the Department does not receive a response to the request. The manner in which requests are received and the lack of response when the Department requests additional information from the researcher makes it difficult to distinguish whether a request has been denied or withdrawn.
6VAC35-170-200	N/A	Grants the Department the discretion to allow periodic reports on research project progress.	Adds a requirement that the researcher submit an annual progress report to the coordinator of external research when the research is not completed within one year of approval. This requirement is intended to encourage the researcher to move the project forward in a timely manner.
6VAC35-170-220	N/A	Requires the Department to direct that the researcher submit up to 10 copies of the formal final report to the coordinator of external research, which must contain the following statement: "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."	Amends the language to allow the Director to waive the inclusion of this statement. In some cases, the Department may wish to maintain anonymity with respect to the results of the study, and the inclusion of this statement would be counterproductive.