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# **Proposed Regulation Agency Background Document**

| Agency name                                    | Department (Board) of Juvenile Justice  |  |
|--|---|--|
| Virginia Administrative Code (VAC) citation(s) | 6 VAC35-170   |  |
| Regulation title(s)                            | MINIMUM STANDARDS FOR RESEARCH INVOLVING HUMAN SUBJECTS OR RECORDS OF THE DEPARTMENT OF JUVENILE JUSTICE  |  |
| Action title                                   | 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 et seq.) of Title 32.1 for human research. |  |
| Date this document prepared                    | November 13, 2014   |  |

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 (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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 three types of external data requests and research proposal. These are (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 but provides minimal guidance for research proposals that do not involve human research. Additional language has been proposed to address researchers failing to comply with the requirements of approved proposals.

#### **Acronyms and Definitions**

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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.

Board - State Board of Juvenile Justice Department - Department of Juvenile Justice

#### **Legal basis**

Please identify the (1) the agency (includes any type of promulgating entity) and (2) the state and/or federal legal authority for the proposed regulatory action, including the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable. Your citation should include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Section 66-10.1 of the *Code of Virginia* directs the Department of Juvenile Justice's (Department) 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. Thus, the regulation is mandatory.

The Board is empowered with general authority to promulgate regulations by § 66-10 of the Code of Virginia that states the Board may "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 or the Department."

#### **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.

The Minimum Standards for Research Involving Human Subjects or Records of the Department of Juvenile Justice (6VAC35-170) establishes the regulatory requirements and minimum standards 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 proposed amendments to the regulatory language on November 12, 2014.

The proposed amendments to the regulation provide the public information on the requirements and the decision process for research proposals not involving human research. Additionally, the proposed amendments require researchers report noncompliance with the conditions of the signed research agreements and authorize the Department and Human Research Review Committee to prohibit further research or restrict the publication and use of the data research results.

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#### **Substance**

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of changes" section below.

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 new types of external data requests. These are (1) external aggregate data requests (New Section: 6VAC35-170-62) and (2) external case-specific data requests (New Section: 6VAC35-170-65). 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 amendment to the public is providing the public with the requirements and decision process for research proposals not involving human research. Additionally, language has been proposed requiring an additional layer of review to ensure juvenile information is adequately protected when providing deidentified 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 research proposals conducted or supported by a federal agency establish an institutional review board (IRB) to review research proposals and determine if 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.

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### 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.

#### **Public participation**

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the Board is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the Board is 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 written comments for the public comment file may do so by mail, email, or fax to Barbara Peterson-Wilson, Regulatory and Policy Coordinator, P.O. Box 1110, Richmond, VA 23218, 804-588-3902 (office), 804-371-6490 (fax), and Barbara.Peterson-Wilson@djj.virginia.gov. Comments may also be submitted through the Public Forum feature of the Virginia Regulatory Town Hall web site at: http://www.townhall.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will not be held following the publication of this stage of this regulatory action.

# **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 requirement creates the anticipated economic impact.

| Projected cost to the state to implement and | The current regulatory language addresses the |
|--|---|
|  |   |

| enforce the proposed regulation, including:                     | Department's responsibilities to review and process      |
|---|--|
| a) fund source / fund detail; and                               | requests for data and human research proposals. The      |
| b) a delineation of one-time versus on-going                    | proposed language provides additional guidance for       |
| expenditures  | these processes; therefore, the Commonwealth will not    |
|   | incur additional costs to implement the proposed         |
|   | amendments to the regulation.                            |
| Projected cost of the new regulations or                        | \$0  |
| changes to existing regulations on localities.                  |  |
| Description of the individuals, businesses, or                  | The Department of Juvenile Justice's state-operated      |
| other entities likely to be affected by the new                 | juvenile correctional centers, Board-regulated juvenile  |
| regulations or changes to existing regulations.                 | secure detention centers and group homes along with      |
|   | students and professors attending universities and       |
|   | colleges within the state of Virginia and throughout the |
|   | country conducting juvenile justice related research     |
|   | will be required to comply with the proposed             |
|   | regulatory requirements governing requests for juvenile  |
|   | data and human research proposals.                       |
| Agency's best estimate of the number of such                    | The Department of Juvenile Justice and its three state-  |
| entities that will be affected. Please include an               | operated juvenile correctional centers, and 24 juvenile  |
| estimate of the number of small businesses                      | detention centers. No small business will be affected.   |
| affected. Small business means a business                       |  |
| entity, including its affiliates, that:                         |  |
| <ul> <li>a) is independently owned and operated and;</li> </ul> |  |
| b) employs fewer than 500 full-time employees or                |  |
| has gross annual sales of less than \$6 million.                |  |
| All projected costs of the new regulations or                   | a) \$0   |
| changes to existing regulations for affected                    | b) \$0   |
| individuals, businesses, or other entities.                     |  |
| Please be specific and include all costs                        |  |
| including:  |  |
| a) the projected reporting, recordkeeping, and                  |  |
| other administrative costs required for                         |  |
| compliance by small businesses; and                             |  |
| b) 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.  | D 11 d 11 2d d 1 2 4 1                                   |
| Beneficial impact the regulation is designed                    | Providing the public with the requirements and           |
| to produce.   | decision process for research proposals not involving    |
|   | human research and ensuring confidential juvenile        |
|   | information is adequately protected when data is         |
|   | provided to researchers.                                 |

#### **Alternatives**

Please describe any viable 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. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

The Department formed a work group to review the current practices related to external requests for data and the process for reviewing human research proposals. The work group recommended developing a process for two types

of external data requests: aggregate data requests and de-identified data requests. The work group also recommended revising the regulations to track the language in Title 32.1 of the *Code of Virginia*. A viable alternative to revising the regulation is to leave the regulation as currently drafted and allow Department procedures to govern the process for external data requests. The proposed amendments to the regulation codify the practice of the Department and therefore do not increase the work of the agency or expand the requirements of the researcher. The proposed regulation does not have an impact on small businesses.

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### Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

The proposed regulation does not have an impact on small businesses. The reporting requirements and the deadlines for compliance, with two exceptions, are requirements and deadlines for Department staff not the public generally or researchers. The reporting requirement for researchers is limited to reporting to the Department or Human Research Review Committee when out of compliance with the research agreement and reporting when a research project extends beyond a year from the date Department data was provided to the researcher.

# Periodic review and small business impact review report of findings

If this NOIRA is the result of a periodic review/small business impact review, use this NOIRA to report the agency's findings. Please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review and (2) indicate whether the regulation meets the criteria set out in Executive Order 17 (2014), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable. In addition, as required by 2.2-4007.1 E and F, please include a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

| Commenter         | Comment                                    | Agency response                                |
|-------------------|--|--|
|                   | I hope it brings better results. Let's see | Thank you for your comments. The Department is |
| Heber, M. Student | if all this cocludes and gives some        | working to improve the minimum standards for   |
| Services          | results or it just remains a useless       | research involving human subjects through a    |
|                   | discussion on this.                        | comprehensive review of the regulations.       |
| May Anderson      | Keep up the great work! I am sure          | Thank you for your comments                    |
|                   | results will follow soon.                  |  |
| Cameron Fenley    | I object. I object the decision for        | Thank you for your comments. The Department is |
|                   | reviewing this regulation as the existing  | working to improve the minimum standards for   |
|                   | one already provides lots of beneficial    | research involving human subjects through a    |
|                   | things like the existing redulation        | comprehensive review of the regulations.       |

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|----------------|---|---|
|                | requires a review committee, deal room, consent from human subjects, annual reports to the Governor and many other things. This regulation should not be changed.                     |   |
| Todd Owen      | Very interesting. Again, will the results be best for the citizens? Let's hope our elected officials are thinking about the citizens!   | Thank you for your comments. The Department is working to improve the minimum standards for research involving human subjects through a comprehensive review of the regulations.  |
| Kelly J        | RE. Where can I uncover more information about this please?   | Thank you for your comments. Information related to the stages of the administrative process can be found on the Virginia Regulatory Town Hall website http://townhall.virginia.gov. Regulations related to the human subject research can be located in Title 6, Agency 35, Chapter 170 in the Virginia Administrative Code. |
| Sarah Levins   | Info. I agree with Kelly. More information is needed for citizens of Virginia to review before this should go through. Can anyone point me to a resource where it is detailed better? | Thank you for your comments. Information related to the stages of the administrative process can be found on the Virginia Regulatory Town Hall website http://townhall.virginia.gov. Regulations related to the human subject research can be located in Title 6, Agency 35, Chapter 170 in the Virginia Administrative Code. |
| Merrill        | No objection. I totally disagreed with Fenley its really needed to review human research projects.  | Thank you for your comments. The Department is working to improve the minimum standards for research involving human subjects through a comprehensive review of the regulations.  |
| Frederik Friis | Interesting with this regulation. I think this is important regulation and I interested with the regulation. Good regulation and good people. Thanks.                                 | Thank you for your comments. The Department is working to improve the minimum standards for research involving human subjects through a comprehensive review of the regulations.  |

The regulation establishes the minimum standards for external data requests and research on human subjects who are under the care or supervision of Department or other Board regulated programs or facilities. The regulations remain necessary to protect the safety, rights, and confidentiality of human research subjects. Additionally, § 66-10.1 of the *Code of Virginia* directs the Department of Juvenile Justice's (Department) 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 regulation is mandatory and remains necessary. The comments received included supporting the review and opposing the review of the regulation. Additionally comments asked where they could obtain additional information on the regulation. The regulation is not complex. The requirements for research proposals and the review process for data requests and human research proposals are outlined in the regulation. The regulation underwent a periodic review July 8, 2011. The regulation tracks state law regarding human subject research and is not in conflict with federal law.

#### **Public comment**

Please <u>summarize</u> all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

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| Commenter | Comment | Agency response |
|-----------|---------|-----------------|
|           |         |                 |

The NOIRA was published in the Virginia Register of Regulations on April 21, 2014. The public comment period ended on May 21, 2014. No public comments were received.

#### **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 juvenile. As such, it maintains parental 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 does not strengthen or erode marital commitment or increase or decrease disposable family income.

# **Detail of changes**

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please list separately: (1) all differences between the pre-emergency regulation and this proposed regulation; and 2) only changes made since the publication of the emergency regulation.

For changes to existing regulation(s), use this chart:

| Current<br>section<br>number | Proposed<br>new section<br>number, if<br>applicable | Current requirement   | Proposed change, intent, rationale, and likely impact of proposed requirements  |
|------------------------------|---|---|---|
| N/A                          | N/A   | Minimum Standards for<br>Research Involving Human<br>Subjects or Records of the<br>Department of Juvenile Justice | New Title Name: Regulation Governing Minimum Standards for Juvenile Information Requests from and Research Involving Human Subjects within the Department of Juvenile Justice. The new title begins with requests for juvenile information and ends with human research requests because within the sequence of the |

|         | <u> </u>                       |  |
|---------|--------------------------------|--|
|         |                                | proposed language requirements for data      |
|         |                                | requests are discussed prior to requirements |
|         |                                | for human research proposals.                |
| 6VAC35- | Terms used within the regulati |  |
| 170-10  | are defined.                   | to ensure the public understands the meaning |
|         |                                | of terms used throughout the regulation:     |
|         |                                |  |
|         |                                | "Aggregate data" means statistics, which     |
|         |                                | 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.                                  |
|         |                                | "Case-specific data" means non-              |
|         |                                | aggregated data that provides information    |
|         |                                | about individuals within a group.            |
|         |                                | "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.                            |
|         |                                |  |
|         |                                | "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.             |
|         |                                | "External research" means research           |
|         |                                | conducted at or using the resources of a     |
|         |                                | _  |
|         |                                | facility, program, or organization that is   |
|         |                                | owned, operated, or regulated by the         |
|         |                                | Department 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.                            |
|         |                                | "Human Research Review Committee"            |
|         |                                | means the committee established by the       |
|         |                                | _  |
|         |                                | Department to oversee human research         |
|         |                                | proposals and activities in accordance       |
|         |                                | with section 130 of this regulation and §    |
|         |                                | 32.1-162.19 of the Code of Virginia.         |
|         |                                | "Written" means the required information     |
|         |                                | is communicated in writing. Such writing     |
|         |                                | m mmg. sum mining                            |

|                    |                   |  | may be available in either hard copy or electronic form.  The definition of human research was amended to match the definition in § 32.1-162.19 of the <i>Code of Virginia</i> .   |
|--------------------|-------------------|--|--|
| 6VAC35-<br>170-30  |                   | The research shall conform to the standards of ethics 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. | Add the American Evaluation Association to the list of professional association ethics that are complied with. Most research proposals have an evaluation component the association was added to address this component of research proposals.   |
| 56VAC35-<br>170-50 |                   | Projects meeting the listed conditions are required to be approved.  | 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.  Language was added to clarify that a proposal may only be approved if the conditions are met.  Language added requiring the data requests comply with all Department procedures. |
|                    | 6VAC35-170-<br>62 |  | Language added describing the process for reviewing and determining approval or denying approval for a request for aggregate data.  Aggregate data requests meeting regulatory and Department procedural requirements will be reviewed and approved or denied by the coordinator of external research within 20 business days. The proposed section allows aggregate data requests to be reviewed and processed in a timely manner by the Coordinator of External Research.  |

|         | 6VAC35-170-<br>65 |  | Language added describing the process for reviewing and determining approval or denying approval for a request for external case-specific data.  Requires a committee designated by the Director to:  O 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.  O Determine the research is beneficial to the Department.  Ensure juvenile confidential information will be adequately protected.  Make a recommendation to the                                     |
|---------|-------------------|--|---|
| 6VAC35- |                   | Informed consent is required to  | Director or his designee to approve or disapprove the request.  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 the identifiers listed above for research benefiting the Department.  Requires juvenile record information provided to the researcher to be encrypted.  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. |
| 170-80. |                   | be given in writing by the subject if competent, by the authorized legal representative if not competent or if a minor | who are able to provide consent both individuals must consent to all the subject to participate in human research.  Language added to make the section more consistent with informed consent requirements stated in § 32.1-162.18 of the Code of Virginia.  |

| 6VAC35-<br>170-100 |                    | Endorsements are required but there is no requirement the endorsement be in writing.   | Language added requiring endorsements from the heads or organizational units, juvenile and domestic relations judges, and institutional review boards are in writing.  |
|--------------------|--------------------|--|--|
| 6VAC35-<br>170-120 |                    | Department staff shall review research proposals that do not involve human research and make a recommendation to the Director within 30 days of receiving the proposal. The Director shall approve or deny the proposal within 10 days of receiving the recommendation | Section deleted: Proposed sections on aggregate data requests (6VAC35-170-62) and case-specific de-identified (6VAC35-170-65) data requests address research proposals not involving human research.   |
| 6VAC35-<br>170-140 |                    | The human research review committee will review human research proposals within 30 days of receiving the completed proposal.   | Clarifies 30 days are 30 business days   |
| 6VAC35-<br>170-170 |                    | The Director will approve or deny the proposal within 10 days of receiving the committee's recommendation.   | Clarifies 10 days are 10 business days   |
|                    | 6VAC35-170-<br>185 |  | Language added requiring the researcher to report noncompliance.  Language added describing the consequences for researchers not complying with state statutes, regulations, or Department procedures governing external research.   |
| 6VAC35-<br>170-190 |                    | Requires the Department report to the Board a summary of research proposals that were not approved.  | Deleted the language requiring the Human Research Review 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 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 requests. The fashion in which requests are received and the lack of |

|                    |  | response when the Department requests additional information from the researcher makes is difficult to determine when a request has been denied.   |
|--------------------|--|--|
| 6VAC35-<br>170-200 | The Department can request periodic reports on the progress of the research project.   | Language added requiring the researcher submit an annual progress report when the research is not completed within one year of approval.  Requiring the researcher to report progress after a year is intended to encourage the researcher to move the project forward in a timely manner.   |
| 6VAC35-<br>170-220 | The Department requires the researcher submit up to 10 copies of the final report. Additionally, all reports 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." | The Director may waive the requirement that the following statement be added to final reports. "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." In some cases it is necessary to remove the statement to protect the identity of juveniles or in cases in which the Department does not agree with the interpretation of the research findings. |

If a new regulation is being promulgated, use this chart:

| Section number | Proposed requirements | Other regulations and law that apply | Intent and likely impact of proposed requirements |
|----------------|-----------------------|--------------------------------------|---|
|                |                       |                                      |   |