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Fast-Track Regulation
Agency Background Document

Agency name	Department (Board) of Juvenile Justice
Virginia Administrative Code (VAC) citation(s)	6 VAC35-170
Regulation title(s)	Regulation Governing Minimum Standards for Juvenile Information Requests from and Research Involving Human Subjects within the Department of Juvenile Justice
Action title	Initiate a fast-track regulatory action to make minor amendments to the process for requesting and approving requests for data and human research proposals
Date this document prepared	November 18, 2019

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations.*

Brief Summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

The Regulation Governing Minimum Standards for Juvenile Information Requests from and Research Involving Human Subjects within the Department of Juvenile Justice (6VAC35-170) establishes the process for submission, review, processing, and approval or denial of research proposals and data requests involving youth served by the Department of Juvenile Justice. This regulatory action seeks to amend various sections of this chapter in order to clarify provisions that have generated confusion among the regulated community and remove invalid provisions consistent with recent regulatory amendments. The proposal adds provisions addressing external case-specific data requests submitted through the Virginia Longitudinal Data System. The proposal also seeks to impose additional requirements to ensure that sensitive data disseminated to external entities are protected from unauthorized access and make

additional revisions aimed at simplifying the language and enhancing understanding and compliance with the regulatory requirements.

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.

"Board" means the Board of Juvenile Justice.

"CSU" means "court service unit," a state or locally operated unit established to provide services to Juvenile and Domestic Relations Courts pursuant to §§ 16.1-233 and 16.1-235 of the Code of Virginia.

"DJJ" means the Department of Juvenile Justice.

"JCC" means juvenile correctional center.

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.

On June 19, 2019, the board authorized the submission of a fast-track regulatory action to amend the Regulations Governing Minimum Standards for Juvenile Information Requests from and Research Involving Human Subjects within the Department of Juvenile Justice. Additional amendments were approved by the Board on November 13, 2019. Currently, these regulations are set out at 6VAC35-170.

Mandate and Impetus

Please identify the mandate for this regulatory change, and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, board decision, etc.). For purposes of executive branch review, "mandate" has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

As required by Virginia Code § 2.2-4012.1, please also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track process.

There is no specific mandate associated with this regulatory change. The proposed amendments are a product of recommendations made by department staff to clarify regulatory provisions that were generating confusion among the regulated community. The board authorized the submission of these amendments through the fast-track regulatory process on June 19, 2019 and November 13, 2019.

The department does not expect these proposed changes to generate controversy. The amendments seek to simplify the process for external researchers to obtain requested data, protect information deemed sensitive, create a separate process for data requests submitted through the Virginia Longitudinal Data System, and provide additional clarity and guidance to the regulated community.

Legal Basis

Please identify (1) the agency or other promulgating entity, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must 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 or promulgating entity's overall regulatory authority.

The promulgating entity is the board. Section 66-10.1 of the Code of Virginia imposes upon the board the duty to promulgate regulations for human research conducted or authorized by the department in accordance with Chapter 5.1 (Title 32.1) of the Code of Virginia.

Additionally, the board is entrusted with general, discretionary authority to promulgate regulations by § 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 regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it's intended to solve.

During the last periodic review and amendment of this chapter, which took effect on December 1, 2016, the board revised the regulation to address how external data requests and research proposals within the Commonwealth's juvenile justice system would be coordinated, reviewed, and approved or denied. Rather than providing clarity and enhancing compliance, some of these changes generated additional confusion among the regulated community or created an unsustainable process for department staff and researchers. The proposed changes are intended to clarify the processes applicable for individuals or organizations seeking to conduct research on or requesting data regarding youth under the authority of the department or a department-regulated facility. These amendments provide the regulated community with needed guidance regarding the requirements for submitting data requests and research proposals and the process for handling and approving or denying these requests. New provisions that further protect sensitive data regarding these youth and that allow for more severe consequences for researchers who fail to comply with approved proposals or laws or regulations are needed to ensure the protection of youth under the care of DJJ or a DJJ-regulated facility or program and will be essential to protect their safety and welfare.

In addition, the department's participation in the Virginia Longitudinal Data System has generated inquiries among staff and researchers as to whether the existing regulatory requirements apply when external data requests for DJJ-maintained data are submitted through the Virginia Longitudinal Data System, or VLDS. VLDS is a data system that seeks to create usable information for policy and generate cross-agency research by providing de-identified case-specific data from various participating agencies to qualified researchers. Researchers submit their data requests through the VLDS portal and work with participating agencies to access whatever data the participating agency elects to make available to the researcher on a case-by-case basis. As the number of requests submitted through VLDS increase, DJJ and researchers should have clear guidance regarding the rules and expectations for submitting such requests.

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 clarifies the scope of the regulatory provisions regarding human research and specifies that individuals under the care, custody, or supervision of a facility or program regulated by the department or the Board of Juvenile Justice, as well as under the care or supervision of the department, may constitute a "human subject" for purposes of this regulation. A conforming change is made in the definition of "organizational unit head" in order to demonstrate that the head of facilities or programs regulated by the department also may endorse human research conducted on residents or youth under their supervision or care.

The proposal identifies an additional form (the Confidentiality Form) that must be submitted to the department for external case-specific data requests. It also strikes a few of the identifiers currently required to be removed from case-specific data before the department or department-regulated facility or program provides this information to researchers, and places restrictions on the director's existing authority to allow the dissemination of data with some of these identifiers.

The proposal also exempts external-case specific data requests submitted through the VLDS from the requirements applicable to other such data requests and establishes new rules for these requests.

The proposal also allows for an expedited review conducted by the chair of the HRRC when minor amendments are made to previously approved data requests.

The amendments add two exceptions to the categories of research exempt from the requirements governing human research to conform to federal regulatory provisions contained in 45 CFR 46.101(b).

Additionally, the proposal removes provisions directing the researcher, as part of the required proposal mandated for external research, to include the endorsement of an academic advisor for student research and the appropriate juvenile and domestic relations judge for records involving juveniles at state and local court service units.

The proposal inserts an additional potential consequence for researchers who fail to comply with the approved proposal or who violate state statutes or regulations. In addition to restricting or terminating further research and prohibiting the researcher from presenting or publishing the research results, as authorized under the existing regulation, the proposal allows the department to bar the researcher from conducting studies in the future.

In order to conform to current law, the proposal requires an overview of the annual report currently mandated in the regulation be completed and posted on the department's website unless the information is exempt from disclosure under the Freedom of Information Act.

Additionally, the proposal strikes every provision in the regulation requiring the regulant to comply with various mandates "**in accordance with department procedures.**" These provisions violate the Virginia Code Commission's 2016 regulation (1VAC7-10-140) prohibiting state agencies from incorporating into their regulations documents established by that agency. To alert regulants to department-developed procedures pertaining to data requests and research proposals, the amendments add a new section that allows the department to establish written procedures to comply with the regulatory requirements contained in this chapter and that requires the department to place such procedures on its website.

Finally, the proposed amendments include several additional minor changes intended to promote clarity including, for example, establishing a new term ("internal committee"), to distinguish between the human research review committee and the committee that oversees de-identified case specific data;

incorporating language from federal or state statutes into the regulation, rather than simply referencing the statute; and clarifying which individuals are responsible for duties outlined in the regulation.

Issues

Please identify the issues associated with the regulatory change, 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, include a specific statement to that effect.

The proposed amendments will promote uniformity for department-regulated facilities and programs seeking to respond to external data requests and research proposals for youth under such facilities' care. The action will help to protect sensitive data and ensure that protected records and information concerning court-involved youth remain confidential. Additionally, the proposal will ensure that the department's regulations more closely reflect federal and state statutes and regulations. The proposal also removes several needless, impractical, and burdensome requirements that tend to delay or hamper research efforts. These changes may help to advance research that ultimately could reduce recidivism and otherwise benefit the public and court-involved youth in the Commonwealth.

Allowing the department to bar the researcher from conducting studies in the future, however, could quell such research efforts, which ultimately may harm the public.

Requirements More Restrictive than Federal

Please identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and 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 specific statement to that effect.

Section 66-10.1 of the Code of Virginia directs the board to promulgate regulations to effectuate the provisions of Chapter 5.1 (§ 32.1-162.16 et seq.) of Title 32.1 regarding human research 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 (HRRC). This adds a new step to the human research approval process, which makes the current regulations more restrictive than the federal requirements. By extension, any additional requirements imposed on the HRRC pursuant to these amendments also will be more restrictive than federal requirements. Therefore, new language requiring the HRRC to review requests that include sensitive data is more restrictive than federal regulatory requirements.

Additionally, the provision giving the department the authority to bar researchers who fail to comply with the approved proposal or violate state law or regulations is more restrictive than federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Please identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected

The proposal will impact participating agencies that are part of the VLDS to the extent that researchers request data from DJJ that may be linked with other participating agencies. Participating agencies currently include the Virginia Department of Education, the State Council of Higher Education for Virginia, the Virginia Employment Commission, the Virginia Department of Social Services, the Virginia Community College System, the Virginia Department for Aging and Rehabilitative Services, and the Virginia Department of Health Professions (DHP). The proposed changes are not expected to impact other state agencies.

Localities Particularly Affected

The proposal will impact local facilities that operate juvenile detention centers, group homes, and similar facilities regulated by the department, to the extent they receive research proposals and data requests regarding residents or youth in their programs. The department currently regulates 24 locally operated juvenile detention centers and 16 group homes or other nonsecure residential facilities.

Other Entities Particularly Affected

The proposal will impact residents, staff, and contractors in juvenile correctional centers or other department-regulated programs or facilities who are proposed subjects of human research or on whom data are collected.

Economic Impact

Pursuant to § 2.2-4007.04 of the Code of Virginia, please identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Please keep in mind that this is change versus the status quo.

Impact on State Agencies

For your agency: projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	The proposed amendments are not expected to result in increased costs for DJJ. Rather, the amendments have the potential to save time and DJJ resources by increasing efficiency throughout the process. Unqualified individuals will be identified and screened out earlier in the process. Similarly, researchers who fail to comply with requirements may be restricted from applying for other research projects. The director,

	the HRRC, and members of the internal review committee will conserve resources by foregoing the review or approval of minor amendments to previously approved data requests and data requests submitted through the VLDS. Because the department cannot predict the number of such future data requests or amendments, the magnitude of potential savings cannot be determined.
For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	The proposal may impact other state agencies participating in the VLDS; however, the department does not expect these agencies to incur additional costs as a result of the proposed amendments.
For all agencies: Benefits the regulatory change is designed to produce.	The regulatory change is designed to simplify and clarify the process for requesting data or making human research proposals through the department's juvenile correctional centers or other department-regulated facilities or programs.

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	While the proposal is expected to impact locally operated detention centers, group homes, and other DJJ-regulated facilities, the department does not expect localities to incur additional expenses or fees. Nor is the proposal expected to have a direct, meaningful impact on local revenues.
Benefits the regulatory change is designed to produce.	The regulatory change is designed to clarify and simplify the protocol for processing data requests and research proposals involving residents in these local facilities and programs.

Impact on Other Entities

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	The proposed amendments will impact individuals and entities conducting research or seeking data on court-involved youth, youth committed to the department of juvenile justice, and youth under the supervision or custody of department-regulated facilities. The proposal will impact staff in research institutes and professors and students in educational institutions, among other individuals. Expedited reviews and approvals for VLDS submissions and minor amendments to previously approved data requests will benefit researchers by reducing the time for processing these submissions. Additionally, the proposal will impact court-involved youth committed to DJJ, under custody of a DJJ-regulated facility, or under supervision of a court service unit, as well as their family members. Finally, staff and contractors in these facilities and programs may be impacted.

Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	The department cannot estimate the number of such entities or individuals that will be impacted by the proposed amendments. In Fiscal Year 2018, the department received eight research proposals from universities and research institutes. The department has no way of estimating the number of entities that will submit research proposals or data requests in the future, nor the number of youth under the care of the department or its regulated entities that will be impacted by the proposed amendments.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Please be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	Although the proposal may result in additional administrative tasks for researchers, any associated expenses generated from these tasks likely will be insignificant.
Benefits the regulatory change is designed to produce.	The proposal clarifies and simplifies the submission and review process for parties submitting data requests and research proposals through the department. The proposal seeks to protect youth under the care or supervision of the department or its regulated facilities or programs by: (i) preventing the unauthorized disclosure of confidential records and information; (ii) prohibiting researchers from engaging in research activities that violate federal or state law or regulations; and (iii) barring or restricting researchers who fail to comply from conducting research in the future.

Alternatives

Please describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. 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 regulatory change.

The agency considered several alternatives to amending the regulation that would address the confusion generated by the 2016 regulatory amendments. One viable alternative to revising the regulation is to leave the regulation as currently drafted and amend department procedures to address this confusion. Amending the department's related written procedures to clarify some of the confusing regulatory provisions would be an insufficient solution because the procedures do not carry the weight of agency regulations. Furthermore, the department is prohibited from establishing procedures that are in direct conflict with regulations or that do not meet regulatory requirements. Many changes necessary to address

the issues identified in this form cannot be made at the procedural level unless the board first makes a regulatory change.

Retaining the regulation and the written procedures as they are also would be insufficient because it would leave provisions in place that are invalid or require clarification.

Amending the regulation to clearly define its scope, narrow the identifiers deemed sensitive, establish a separate process for data requests submitted through the VLDS, and allow for additional, more stringent alternatives for researchers who fail to comply with federal and state law is the least intrusive alternative. These amendments will balance the need for protecting subjects of human research with the goal of advancing research that will benefit the department and the youth it serves.

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) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing 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 regulatory change.

The department conducted an analysis of alternative regulatory methods consistent with health, safety, environmental, and economic welfare. The department determined that establishing less stringent reporting requirements or deadlines would not be beneficial given that most such requirements or deadlines fall on the department or its established committees, rather than on the regulant. Researchers are required to report to the HRRC any noncompliance with the approved research proposal and to provide periodic progress reports. Striking these requirements would eliminate valuable information the department needs to determine whether these proposals should be terminated.

To the extent this chapter impacts small businesses, exempting them from the requirements of these regulations would reduce uniformity and be counterproductive to the goal of establishing a clear process for all regulated entities.

Public Participation

If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register; and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

Detail of Changes

Please list all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation.

If the regulatory change will be 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 change. Delete inapplicable tables.

If the regulatory change is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below. Please include citations to the specific section(s) of the regulation that are changing.

For changes to existing regulation(s), please use the following chart:

Current section number	New section number, if applicable	Current requirement	Change, intent, rationale, and likely impact of new requirements
N/A	N/A	The current chapter is titled, Regulation Governing Minimum Standards for Juvenile Information Requests from and Research Involving Human Subjects within the Department of Juvenile Justice.	The board proposes to simplify the chapter title as follows: Regulation Governing Juvenile Data Requests and Research Involving Human Subjects
10	N/A	**Definitions**: The current definitions governing data requests and human research proposals are provided in Section 10 (definitions) and include the following terms: **aggregate data** (*statistics related to broad classes, making individual properties indistinguishable)*; **case-specific data** (*nonaggregated data)*; **coordinator of external research** (*DJJ director-designated staff who receives and reviews research proposals)*; **de-identified data** (*data with common identifiers removed*); **department** (*of juvenile justice*); **director** (*of the department)*; **encrypted** (*data transformed into a form that is meaningless without a confidential process or key)*;	The board proposes the following amendments to the existing terms: **-Coordinator of external research** – adds to this position's duties the receipt of external data requests. **-Director** – expressly includes the director's designee as well as the DJJ director under this definition. -**Human subject** – expands this term to include proposed subjects of research who are under the care, custody, or supervision of facilities or programs regulated by the department as well as employees and contractors serving facilities or programs operated or regulated by DJJ. -**Organizational unit head** – expands this term to include heads of board-regulated facilities, programs, or services, in order to ensure that JDCs and other DJJ-regulated facility heads also fall under this definition. -**Principal researcher** – for purposes of clarification, changes one of the principal researcher's oversight responsibilities

		external research (*research at DJJ or using resources of DJJ/Board-owned, operated, or regulated programs or facilities conducted by outside parties);* **human research** (*systematic investigation using human subjects to develop generalized knowledge, excluding research exempt from federal research regulation);* **Human Research Review Committee** (*DJJ-established committee that oversees human research proposals);* **human subject** (*subject of human research who is under DJJ's care, custody, or supervision or subject's family member)*; **informed consent** (*knowing and voluntary agreement without undue constraint or coercion)*; **legally authorized representative** (*custodial parent, legal guardian, or other person legally authorized to consent on a prospective subject's behalf*); **minimal risks** (*risks of anticipated harm from proposed research are not greater than risks in daily life or during routine physical or psychological exams*); **nontherapeutic research** (*human research with no expectation of direct benefit to human subject's physical or mental condition)*; **organizational unit head** (*person in charge of a JCC, CSU, or other DJJ organizational unit)*; **principal researcher** (*person responsible for the research design and conduct, research staff supervision, and research findings)*; **research** (*systematic development of knowledge essential to effective planning and rational decision-making, the findings of which should*	from the ***conduct*** of research to the ***implementation*** of research. -**Research** –removes as unnecessary the requirement that research provide valuable information to management for policy options. The proposal adds the following terms: -**Internal committee** – DJJ-established committee to oversee de-identified case specific data. -**Sensitive data** – data which, if compromised, could have a material adverse effect on agency programs or individual privacy. -**Virginia Longitudinal Data System** or **VLDS** – data system providing de-identified case-specific data from participating agencies to researchers through process in which requests are approved or denied by each sponsoring agency from which data are sought. The proposal makes non-substantive style changes to the following terms: **de-identified data**, **external research**, **human research review committee, legally authorized representative,** and **written**. The proposal removes the following term from Section 10 due to infrequent use: **encrypted**.

		provide valuable information to management for policy options); ***researcher*** *(individual conducting research)*; **research project** (*systematic collection of information, analysis of data, and preparation of findings*); and **written** (*information communicated in writing, manually or electronically*).	
20	N/A	**General requirements of external researchers**: This section makes the principal researcher responsible for providing information required by the Human Research Review Committee, among other parties.	The proposal replaces all references to the Human Research Review Committee here and throughout this chapter (see Sections 20, 65, 70, 80, 110, 130, 140, 150, 160, 170, 180, 185, and 190) with its acronym, HRRC, so that there is a clear delineation between the HRRC and the committee established to oversee de-identified case-specific data. The proposal makes other minor nonsubstantive changes to this section, which will not impact youth or staff in DJJ-regulated facilities and programs.
50	N/A	**Conditions for department approval of external research**: The department must ensure that certain conditions are satisfied before it may approve research projects, including that there are sufficient financial and staff resources to sustain the research, that the research will not interfere with DJJ programs or operations, that it is compatible with the purposes and goals of the justice system, and that it complies with DJJ procedures, which must be posted on its website.	The proposal clarifies that these pre-conditions must be satisfied in order for the department to approve data requests as well as external research proposals. This requirement is set out in Section 50 but should also be clarified here. Because the amendment is intended to provide clarity, it will not have an additional impact on youth or staff in DJJ or DJJ-regulated facilities and programs. The proposal also strikes the requirement in this and other sections that the data requests and research proposals accord with department procedures. This provision is in conflict with the 2016 Virginia Code Commission's regulation (1VAC7-10-140), which prevents state agencies from incorporating their own documents into regulations by reference. Individuals and organizations submitting research proposals or data requests must comply with DJJ's applicable procedures as standalone documents. These procedures are not regulations and may not be incorporated into the regulation by reference.
60	N/A	**Formal agreement required**: Researchers may not commence external research until all the reviews	The proposal clarifies that this provision applies to case-specific data requests and human research requests. Additionally, the proposal strikes the

		required in this chapter and by department procedure are completed.	invalid reference to the department's procedures pursuant to the 2016 Virginia Code Commission's regulations. The proposal makes several additional, nonsubstantive changes, which are intended to promote clarity and are not expected to have additional impact.
62	55	**Review and approval of aggregate data requests**	The proposal moves the provision regarding the process for reviewing and approving aggregate data requests into a new Section 55 for structural purposes. Because its content has been moved, Section 62 can be repealed. The proposal also strikes the requirement that aggregate data requests be submitted in accordance with department procedures. The proposal makes additional, nonsubstantive changes, which will have no additional impact.
65	N/A	**External case-specific data requests:** (A) Researchers must submit external case-specific data requests to the department via the Research Proposal Form, the Research Agreement Form, and any attachment required by department procedures. (C) The coordinator of external research must review this information and determine, among other things, that the proposal is not human research subject to HRRC review. (D) The department must remove certain identifiers from the data before disseminating data to researchers. Currently, these identifiers include names; dates (of birth, admission, release, etc.); postal address information, excluding town or city, state, and zip code; telephone numbers; social security numbers; medical record numbers; account numbers, such as Juvenile Tracking System numbers and Direct care numbers; biometric identifiers; and full face photographic images and comparable images. (E) The director may allow for the dissemination of data that	(A) The proposal adds the Confidentiality Agreement Form to the list of forms that must accompany an external case specific data request and removes the provision requiring the researcher to submit other attachments required by department procedures. (C) The proposal adds language directing the HRRC to review case-specific data requests if they include sensitive data. (D) The proposal strikes the following from the list of identifiers that must be removed before data are disseminated: (i) dates of admission and dates of release; and (ii) account numbers. These categories are not sensitive by nature; they become sensitive only when paired with additional identifiers or other information. Mandating that they be removed from the data has unnecessarily burdened department resources and created a scenario where the director's authority, discussed in subsection (E), below, becomes the rule, rather than the exception. The proposal also adds email addresses to the list of identifiers deemed sensitive. (E) The proposal narrows the director's authority to approve the dissemination of data containing some identifiers only to those occasions when the researcher agrees to maintain the confidentiality of such information or to release or publish only the aggregated form of the data. This adds another layer of protection to

		includes a limited number of the identifiers listed in subsection (D) for research benefiting the department. (H) The director must designate a committee to meet within 20 business days of receiving the external case-specific data request to review the data requested and make a recommendation to the director to approve or disapprove the request.	ensure any disseminated data will be protected. (H) The proposal clarifies that the recommendation the internal committee makes to the director must be written. These changes will reduce some of the administrative burdens associated with external-case specific data requests and help to ensure that sensitive data approved for dissemination are protected. (L) The proposal adds language expressly exempting external, case-specific data requests from the requirements of this section and creates a new Section 67, which will apply for such requests.
N/A	67		**Virginia Longitudinal Data System Requests**: This new section establishes separate rules for external case-specific data requests submitted through the VLDS. This separate provision will provide a streamlined process and prevent such requests from having to undergo review or approval by the director or the internal committee. The following new rules apply: (A) Such requests must be submitted using the VLDS portal; (B) The researcher must comply with VLDS procedures to access such data, (C) The chair of the HRRC has primary responsibility for reviewing and approving DJJ requests submitted through the VLDS portal and may not approve requests if they: (i) fail to satisfy the conditions for department approval of research; (ii) are deemed human research proposals; (iii) are not in the required format or exclude any required information; (iv) do not comply with basic research standards or applicable laws; and (v) are not accessible and available. (D) The chair of the HRRC may restrict the scope of the data if it is unrelated to the purpose of the research study. Giving the chair of the HRRC primary authority to review and approve requests submitted through the VLDS portal will remove the logistical challenges and potential delay associated with having the internal committee members, who do not have access to the VLDS portal, conduct a review of these requests.

N/A	69	N/A	**Minor amendments to data requests or research proposals**: This new provision allows the chair of the HRRC to conduct an expedited review of minor amendments to external data requests previously approved by the director, without undergoing an additional review by the internal committee or director. The provision applies solely for minor amendments that do not alter the scope of the request or proposal. The change will relieve the internal committee and the director from having to review and approve minor amendments to research proposals and data requests, and will reduce the time needed to process these minor changes.
70	N/A	**Requirements specific to human research**: This section establishes provisions specific to human research projects including, for example, prohibiting human research involving substantive physical, mental, or emotional risk to subjects and authorizing incentives for participation in human research.	The proposal imposes an additional requirement on researchers to comply with appropriate security and non-disclosure requirements where sensitive data are provided as part of human research. This proposal reiterates the importance of ensuring that sensitive data remain secure from unauthorized access. The proposal makes other nonsubstantive changes that will have no impact.
80	N/A	**Informed consent required for human research (§ 32.1-162.18 of the Code of Virginia)**: This section sets out the informed consent requirements for human research, consistent with the applicable provisions in state law. The provision enumerates the consent requirements for subjects who are competent, incompetent, minors, and where two legally authorized representatives disagree.	The proposal adds language currently set out in § 32.1-162.18 of the Code to clarify that researchers must obtain informed consent of the human subject or his legally authorized representative before involving subjects in human research. This language provides context for the existing regulatory requirements and is consistent with current law. The proposal also removes the statutory references contained in the catchline and elsewhere in this section. These references are unnecessary because Section 70 requires all human research to comply with § 32.1-162.16 *et. seq*.
90	N/A	**Exemptions from the requirements governing human research**: Several categories of human research (including, for example, certain research involving educational strategies, interview procedures, and the observation of public behavior) are exempt from the state statutory provisions	The proposal removes as unnecessary the statutory reference to § 32.1-162.17. This change will have no impact. The proposal also mandates that the listed exemptions be subject to the department's nonhuman research review process rather than making such process discretionary. This change provides for a more uniform method for addressing exemptions from the human research review and approval process.

		governing human research and, by extension, from this regulatory chapter. By regulation, these exemptions **may** be subject to the nonhuman research review process established by the department.	The proposal adds two provisions reflecting the federal regulation, 45 CFR 46.101(b). Under federal regulation, the listed exemptions do not apply to: (i) research on individuals involuntarily confined in penal institutions, including juvenile facilities; and (ii) for the exemption pertaining to research involving the observation of public behavior, research on children under age 18. These changes reflect the federal provisions and are not expected to have additional impact.
100	N/A	**Proposal for external research**: (A) Researchers proposing to conduct external research must present a preliminary research proposal and obtain endorsement from the organizational unit head of the unit in which the research will take place, in accordance with written procedures. (B)(1) When submitting the external research proposal, the principal researcher must include the name, address, telephone number, title, and affiliation of the principal researcher as well as the name of any other person who will immediately supervise the project. (B)(11) A student researcher, when submitting his research proposal, must include an endorsement from the researcher's academic advisor or other appropriate person. (B)(12) When seeking records of juveniles at state and local CSUs, the researcher must submit a written endorsement from the appropriate J&DR judge.	(A) The proposal strikes the invalidated requirement that the proposal accord with written procedures. A new Section 230 is added that requires the department to establish written procedures regarding the process for obtaining the unit head's endorsement. (B) The proposal requires additional contact information be added to the external research proposal, including the principal researcher's email address and the telephone number and email address of the person who will **coordinate**, rather than **supervise**, the project. These minor changes, while not likely to have significant impact, will give the coordinator of external research additional information that may be useful during the review process. (B)(11) The proposal removes the student's duty to obtain the academic advisor's endorsement for student research. This provision suggests that a student would be permitted to serve as a principal researcher, which is inconsistent with current practice. (B)(12) The proposal also strikes the provision requiring a J&DR judge's endorsement for records of juveniles at CSUs. This provision requires judges to provide an endorsement for information that may fall outside their general knowledge and may be better handled by CSU staff.
110	N/A	**Initial review by coordinator of external research**	The proposal makes minor style edits.
130	N/A	**Human research review committee**	The proposal replaces all references to the human research review committee with the HRRC and strikes the unnecessary reference to the statutory

			provision governing such committees. These changes will have no impact.
140	N/A	**Timeline for review of human research proposals** (B) Upon the researcher's request, the HRRC may conduct an expedited review when the proposed human research will involve no more than minimal risk to the subjects and: (1) another agency's HRRC has approved the proposal or (2) the review involves only minor changes to a previously approved research project.	The proposal adds a new subsection C that provides additional information concerning the expedited review process for previously approved human research projects involving minor changes. The chair of the HRRC must provide written approval before the amended project may proceed. The director is not required to review or approve these minor amendments. The proposal also makes minor style edits.
150	N/A	**Committee review of human research proposals**: The human research review committee may recommend approval of human research proposals only when the research complies with the requirements set out in applicable department policies and procedures.	The proposal removes the reference to department policies and procedures, as this requirement is invalidated pursuant to 1VAC7-10-140. The proposal makes additional edits for style. These changes will have no additional impact.
160	N/A	**Committee review of informed consent provisions**	The proposal makes minor style edits.
170	N/A	**Recommendation to director and final action**: Once the HRRC reviews the research proposal and makes a recommendation to the director, the director must approve or deny the proposal within 10 business days of receipt of HRRC's recommendation.	The proposal imposes an additional explicit duty on the coordinator of external research to notify the principal researcher of the director's final decision. This will ensure that researchers are aware of the director's decision and can determine whether to proceed with the proposed human research. Because this requirement currently is set out in the department's applicable procedures, the proposal will not have an additional impact.
180	N/A	**Annual review of human research activities**	The proposal makes minor style edits.
185	N/A	**Researcher noncompliance**: If the HRRC or DJJ determines that the research does not comply with the approved proposal or violates state law or regulations, the department may restrict or terminate further research and prohibit the researcher from presenting or publishing the research results.	The proposal adds an additional potential consequence for research activities that fail to comply with the proposal or violate state statutes or regulations. In such cases, the department also may bar the researcher from conducting studies in the future. This change is intended to incentivize compliance with the researcher's approved proposal, as well as statutory and regulatory provisions. The proposal may reduce the number of future research requests the department

			is required to process and may inhibit a noncompliant principal researcher's future research efforts. The proposal makes other minor edits that will have no additional impact.
190	N/A	**Committee reports required**: The HRRC must provide the Governor, the General Assembly, the DJJ Director, and the Board of Juvenile Justice an annual report on the human research projects it approves.	The proposal adds language to reflect the statutory requirement in § 32.1-162.19(E) of the Code of Virginia directing DJJ to ensure that an overview of the annual report on human research projects be completed and posted on the department's website unless exempt from disclosure under the Freedom of Information Act. Because the proposal reflects current law, it will not have additional impact.
200	N/A	**Progress reports:** If the department requires periodic progress reports for research projects or other supplemental information, the reports must be provided in a timely manner.	The proposal removes the directive that such information be provided in a timely manner as vague and unnecessary. The department establishes timelines for the provision of information in its applicable written procedures, and any delay on the part of the researcher will hinder the research process. It is not necessary for this area to be regulated.
220	N/A	**Final report**: The department must require a formal final report be submitted to the coordinator of external research.	The proposal clarifies that the duty to submit this final report rests with the principal researcher. The proposal makes an additional, minor change for nonsubstantive purposes. These changes will have no additional impact.
N/A	230	N/A	**Written procedures**: This new provision requires DJJ to establish written procedures regarding the process to obtain unit head endorsement for external research proposals. The proposal also gives the department the discretion to establish additional procedures to supplement the regulatory requirements set out in this chapter. Finally, the proposal directs the department to ensure any such written procedures are posted on its website. These changes will help to ensure the regulated entity is aware of existing department procedures regarding the process for obtaining this endorsement without actually incorporating these procedures into the regulation.