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Final Regulation Agency Background Document

Agency name	Department (Board) of Juvenile Justice
Virginia Administrative Code (VAC) Chapter citation(s)	6 VAC35-170
VAC Chapter title(s)	Regulation Governing Juvenile Data Requests and Research Involving Human Subjects
Action title	Periodic Review of the Regulation Governing Juvenile Data Requests and Research Involving Human Subjects
Date this document prepared	April 17, 2026

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Brief Summary

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.

This regulatory action was prompted, in large part, by a periodic review of the Regulation Governing Juvenile Data Requests and Research Involving Human Subjects (6VAC35-170). The action seeks to make comprehensive amendments that will simplify the chapter; clarify processes for submitting, reviewing, and approving external data requests and research proposals; and reduce the chapter's regulatory requirements in furtherance of Executive Order 19, issued by the previous administration, which requires state agencies to reduce their regulatory requirements by 25%. The regulatory action also proposes several changes to ensure the enforceability of certain requirements contained in a supplemental guidance document but not addressed in the regulation and to establish processes for various data requests and projects that are not addressed in the current chapter.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.

"DJJ" means the Department of Juvenile Justice.

"FOIA" means the "Virginia Freedom of Information Act," as set out in § 2.2-3700 et seq. of the Code of Virginia.

"FY" means fiscal year.

"VLDS" means the Virginia Longitudinal Data System.

Statement of Final Agency Action

Provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) that the agency has "adopted final amendments" to the regulation; 3) the name of the agency taking the action; and 4) the title of the regulation. A suggested statement is, "On [insert date] the Board/Department of [insert name] adopted final amendments to the [title of regulation(s)]."

On March 27, 2026, the Board of Juvenile Justice adopted the Department of Juvenile Justice's recommendations for final amendments to the Regulation Governing Juvenile Data Requests and Research Involving Human Subjects (6VAC35-170).

Mandate and Impetus

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding the mandate for this regulatory change, and any other impetus that specifically prompted its initiation. If there are no changes to previously reported information, include a specific statement to that effect.

The proposed regulatory changes were prompted by a periodic review of the chapter conducted by internal Department of Juvenile Justice representatives seeking to identify areas for regulatory reduction in furtherance of Executive Order 19. Additional changes recommended and adopted at the March 27, 2026, meeting are intended to correct minor drafting errors, ensure consistency across regulatory sections, clarify additional confusing provisions, and comply with the Registrar of Regulations' instructions in the Style Manual.

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia and Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

The promulgating agency is the Board of Juvenile Justice.

Section 66-10.1 of the Code of Virginia provides authority for these regulatory amendments by directing the board to promulgate regulations “pursuant to the Administrative Process Act to effectuate the provisions of Chapter 5.1 of Title 32.1 for human research...to be conducted or authorized by the department.

The board is empowered with general authority to promulgate regulations 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

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 is intended to solve.

The Regulation Governing Juvenile Data Requests and Research Involving Human Subjects (6VAC35-170) establishes the process for external entities to submit requests for data or to conduct research on human subjects under the care or supervision of DJJ or other board-regulated programs or facilities. The proposed amendments were offered primarily to assist the agency in its efforts to carry out former Governor Youngkin’s 25% regulatory reduction mandate, as set out in Executive Order 19, and to ensure that each regulatory requirement is necessary to protect the public health, safety, and welfare. The proposed amendments also were expected to enhance existing provisions to ensure the confidentiality of juvenile data maintained by the department. Additionally, the amendments sought to ensure that the department has the necessary information and access to scrutinize research projects involving juveniles and other human subjects and ensure their protection, safety, and privacy. In these ways, the proposed amendments are needed to protect the health, welfare, and safety of citizens.

Substance

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 department recommends adding the following new regulatory sections, as summarized below:

- Section 15, addressing the scope of the chapter;
- Section 17, establishing a process for requests submitted by state criminal justice agencies and external entities conducting research or evaluation at DJJ’s request;
- Section 125, establishing a process for quality or process improvement projects.

The department recommends amendments to the existing regulatory sections, as summarized below:

- Section 20, restricting who may serve as external project lead and modifying their duties;
- Section 30, repealing the provision requiring research conformity with various ethical standards;
- Section 40, removing a restrictive statutory reference and language unnecessarily incorporating policies and procedures;
- Section 50, removing a duplicative consideration in the process for DJJ approval of research or evaluation projects;
- Section 55, repealing the section addressing aggregate data requests;
- Section 60, outlining the submission process for the various projects addressed in this chapter;
- Section 65, (i) eliminating certain determinations and considerations involved with reviewing case-specific data requests, (ii) changing provisions regarding sensitive identifiers; and (iii) correcting language and developing new processes for data requested through alternative portals;
- Sections 65 and 140, eliminating the deadlines for the internal committee and HRRC to review their assigned projects,

- Section 67, (i) expanding the provision's scope to address requests submitted through data trusts, and (ii) changing the requirements for VLDS approvals;
- Sections 69 and 140, limiting the HRRC chair's ability to expedite review and approval of amendments for previously approved data requests and research proposals;
- Section 70, changing the approach for incentivizing research participation and specifying when the Institutional Review Board must endorse projects;
- Section 100, expanding the required information accompanying a human research proposal;
- Section 110, moving one provision and eliminating two provisions to enable the repeal of the entire section;
- Section 130, striking the HRRC's authority to require additional information from the researcher before making a recommendation to the director;
- Section 170, allowing for deferrals of certain recommendations made to the director and setting a deadline for department staff to inform the project lead of the director's decision;
- Section 185, adding a deadline for reporting protocol violations;
- Section 200, granting the department additional flexibility when requesting and considering progress reports;
- Section 210, eliminating the mandate that the Research Agreement give the department unfettered authority to use information generated from the research;
- Section 220, changing the submission requirements for the final report and establishing a waiver process in certain circumstances; and
- Section 230, removing the department's duty to establish procedures regarding the endorsement process; expanding the provision to include quality improvement projects, and striking provisions allowing the procedures to identify additional data elements the department deems sensitive.

Issues

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 provide numerous advantages to the public. Primarily, the proposed amendments will continue preserving and protecting the confidentiality and security of data maintained by the department and protecting juveniles under the department's monitoring, supervision, or care who serve as human subjects for research projects. The proposed amendments also seek to provide greater transparency and clearer guidance by clarifying which forms are required for which requests and proposals, what steps are necessary for requests submitted through VLDS or data trusts, what criteria must be satisfied for the approval of quality or process improvement projects, and the process for expediting the review for approved, modified projects. Clarity in regulations tends to promote enhanced compliance with the regulatory provisions, which, in turn, enhances public protection. The proposal also eliminates regulatory language discouraging researchers from offering incentives for subjects to participate in human research. These deterrents could have a chilling effect on human research that may benefit the department, the youth it serves, and the public at large. Finally, the proposed amendments seek to reduce the burden on regulated entities by reducing the number of requirements contained in the regulation. By removing the regulatory process for submitting aggregate data requests, for example, regulated entities and the department may have greater flexibility in soliciting data and responding to requests.

The proposed amendments also will provide additional advantages to the department. By removing specified deadlines for the internal committee tasked with reviewing case-specific data requests and the HRRC responsible for reviewing human research proposals, the allows gives DJJ flexibility in scheduling

meetings and additional time, if needed, for the committees to conduct their work. Expressly limiting the director's current discretion to release information with a limited number of sensitive data elements within the confines of state confidentiality laws ensures that agency directors will not exceed their statutory authority in responding to requests from external entities, thereby providing greater protection to the department. Enhancing the department's discretion to solicit routine progress reports and other information on the status of research projects allows the department to track and monitor such projects and requests. Finally, including references to the human research statute rather than retaining language that duplicates these statutes eliminates the need for regulatory updates to align with statutory changes and informs the regulated community of the source of the regulatory requirement.

The department does not expect these changes to disadvantage the public. While the amendment to Section 20 seeks to remove the authority for student researchers who lack the requisite standing and qualifications to serve as external project leads when directly supervised by a person with the required credentials, this change operationalizes the department's current practices, and therefore, is not expected to have additional impact.

Requirements More Restrictive than Federal

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any requirement of the regulatory change which is more restrictive than applicable federal requirements. If there are no changes to previously reported information, include a specific statement to that effect.

The department does not consider any regulatory changes proposed in this action as more restrictive than applicable federal requirements. As an example, much like this chapter, federal provisions also allow for an expedited review of human research projects; however, the current federal provision does not authorize expedited review if another IRB has already reviewed and approved the request; therefore, striking the comparable authorization for previously approved research if another HRRC already provided approval does not make this regulation more restrictive than federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any other state agencies, localities, or other entities that are particularly affected by the regulatory change. If there are no changes to previously reported information, include a specific statement to that effect.

Other State Agencies Particularly Affected

State Criminal Justice Agencies - 16.1-300 A 10 authorizes certain specified entities to inspect psychological, social, medical, and psychiatric reports and records of children under DJJ's supervision or care. Among others, the statute applies to state criminal justice agencies conducting research who agree to keep any such information they receive confidential or to release or publish it only in aggregate form. In mandating that such entities complete certain specified forms, the proposed amendments provide such entities with clear guidance for how to access such data. Historically, the department has asked such agencies to complete the research proposal on a case-by-case basis. This regulatory change provides clearer guidance for these entities.

Localities Particularly Affected

No localities will be particularly affected due to these proposed amendments.

Other Entities Particularly Affected

The proposal also will impact entities who contract with the department to conduct research or evaluation at DJJ's request and will be subject to all or a portion of this chapter at the department's discretion.

Public Comment

Summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency's response. Include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency. If no comment was received, enter a specific statement to that effect.

No comments were received during the public comment period following publication of the Proposed Stage, nor were public comments submitted or made at the March 27, 2026, Board of Juvenile Justice meeting addressing this issue.

Detail of Changes Made Since the Previous Stage

*List all changes made to the text since the previous stage was published in the Virginia Register of Regulations and the rationale for the changes. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Put an asterisk next to any substantive changes.*

Current chapter-section number	New chapter-section number, if applicable	New requirement from previous stage	Updated new requirement since previous stage	Change, intent, rationale, and likely impact of updated requirements
170-10	N/A	Definition, human subject – The definition was simplified at the Proposed Stage to include, among others, a member of the family or guardian of an individual recruited for research due to their contact with DJJ or board-regulated facilities or programs.	The updated proposal changes the language to correct an error in drafting. The new language includes, under the definition of human subject, a family member or guardian of the individual recruited for research.	This change is intended to correct an error in drafting and is not expected to have an additional impact.

170-10	N/A	Definition, quality or process improvement project – The definition adopted at the Proposed Stage captured projects intended to monitor, assess, or improve indicators of quality in a program. Under the initial proposal, such project could not include case-specific data requests and were not human research proposals.	The updated proposal makes a minor modification to the language to eliminate what may be perceived as a requirement in the definition. The proposal replaces the language “may not” with “does not,” for these purposes.	The department proposed this change to comply with the Registrar’s directive not to include requirements in definitions. Because “may not” is intended to convey a prohibition, the department opted to replace this language. As the change is intended to clarify the proposed definition, the change is not expected to have additional impact.
170-10	170-15	Definition, external research. At the Proposed Stage, DJJ recommended a new section to exclude from the chapter’s reach research conducted by other “stage” agencies at the General Assembly’s direction. Under the existing regulation, this type of research is excluded from the definition of “external research” in § 10.	The updated proposal corrects the drafter’s error by replacing the term “stage agencies” with “state agencies.”	Correcting this typo will clarify the scope of this chapter. In turn, this clarification is expected to enhance compliance with this chapter.
N/A	170-17	Initially, the department added a new section to clarify the process for and scope of information permitted for release under § 16.1-300 A 10 of the Code. Under this statute, eligible state criminal justice agency researchers may inspect certain confidential juvenile records and reports. Per the amended proposed subsection B, state criminal justice agencies were exempt from	The updated proposal makes a minor change to subsection B, directing state criminal justice agencies to “fill out” rather than “complete” the two specified forms, and requiring them to “follow,” rather than “comply with” the requirements in § 16.1-300.	The minor proposed changes in language align with the Register of Regulations’ Style Guidelines and will provide clearer guidance to the regulated community. Because the proposed changes are not substantive, they will have no additional impact on the regulated community beyond providing additional clarity.

		this chapter's provisions but would need to complete and submit the Data and Research Agreement and Confidentiality Agreement to verify their authority to receive the information		
170-60	N/A	Initially, the department 1) restructured this section to clarify when the three incorporated forms must be submitted to initiate a data request or project; 2) updated two of the forms' names; and 3) added language to enforce provisions in the guidance document. A new subsection A required external case-specific data requests, external research or evaluation project proposals, and quality or process improvement project requests be initiated by completing and signing the Confidentiality Agreement, Data and Research Proposal, and Data and Research Agreement. The proposed new subsection D transferred the required elements of the Research Agreement from Section 65, including the mandatory provision allowing the director to waive the researcher's	A) The updated proposal replaces the reference to "external research or evaluation projects" in subsection A with the term "research projects." D) *The updated proposal strikes the requirement that data requests involving human research have their progress report schedules developed in consultation with the HRRC. E) *The updated proposal no longer seeks to include quality or process improvement projects as part of this restriction and, therefore, strikes the proposed addition. Moreover, the updated proposal adds new language to Section 125 to emphasize the HRRC chair's primary role of reviewing, approving, and signing the Data and Research Agreement for such projects and duplicates language originally proposed in Section 60 prohibiting the external project lead	A) Because the approved amendments at the Proposed Stage define "external research or evaluation projects" to encompass each of these categories of requests, the language separately listing each category and requiring completion of the three forms for each is confusing and redundant, given that all such proposals fall under the broad definition of "external research or evaluation projects." The updated proposal removes this redundancy. D) Because the required content of the Research Agreement is no longer captured in a section limited to case-specific data requests, and expanded Section 60 now seeks to address various other types of projects, the department believes this provision specific to data requests is misplaced. Furthermore, the provision is unnecessary given that the department sets the schedule for these progress reports, which would include input from the HRRC and eliminate the need for this requirement. E) The department believes the board-approved amendment prohibiting regulated

		required disclaimer, and in such cases, compelling submission of all publications at least 30 days before the anticipated release date. The proposal also required agreement language obligating the requester to provide DJJ with annual and additional progress reports according to DJJ's set schedule. For requests involving human research, the proposal required consultation with the HRRC to develop the schedule of progress reports. E) – Initially, the department included quality or process improvement projects among the projects that may not commence until all relevant reviews are completed and the director signs the Data and Research Agreement.	from commencing quality or process improvement projects until all applicable required reviews are completed and the project lead receives the agreement signed by the HRRC chair.	parties from commencing quality or process improvement projects until the director has signed off on the agreement conflicts with proposed Section 125 and is in error. The proposed Section 125 which waives director review of quality or process improvement projects, instead authorizes final approval by the HRRC chair.
170-65	N/A	At the Proposed Stage, the department added a subsection C, in accordance with existing guidance document language, that provided DJJ discretion to treat various identifiers as sensitive and subject to removal based on the project's details and other information in the data set. The categories included subdivision C 1, which notes dates	The updated proposal amends the category in subdivision C 1 to "dates relevant to the juvenile's offenses, programming, or placements."	The minor change to subdivision C 1 is intended to ensure the language is broad enough to encompass the various types of programming and to avoid any inference that the potentially sensitive identifiers apply solely in the context of juveniles in direct care. As this is intended as a clarifying change to the proposed language, the department does not expect the change to significantly impact DJJ operations.

		relevant to the juvenile's offense or placement		
170-65	N/A	At the Proposed Stage, the department clarified the process for external case-specific data requests submitted through the VLDS or a data trust portal. When requests are submitted through the VLDS and DJJ serves as the sponsoring agency or when requests are submitted through a data trust and DJJ's contribution was not mandated by statute, the requests must undergo the process for external case-specific data requests. When DJJ is not the sponsoring agency for a VLDS request or its contribution to the data trust was statutorily mandated, the requesting entities are exempt from the provisions for case-specific data requests. Amendments at the Proposed stage also clarified that all requests submitted through data trusts or the VLDS shall comply with section 67, irrespective of whether DJJ is the sponsoring agency or the origin of DJJ's trust contribution.	The proposal makes a very minor change to require all VLDS and data trust requests to "follow" 6VAC35-170-67, instead of "complying with" such section.	The additional revision is intended to align with the preferred terminology, as set out in the Style Manual.
170-67	N/A	Initially, the board amended the required conditions needed for the	The proposal replaces the language, "include," referencing the final	This minor change is intended to correct a grammatical error. This

		HRRC chair to approve requests submitted through the VLDS or data trust portals to require the requester to agree to give DJJ annual progress reports and a final report with goals for improvement and a plan for changes.	report of findings with “includes.”	style change will have no operational impact.
170-140	N/A	At the Proposed stage, the board removed the 30-business-day deadline the HRRC must follow when reviewing a human research proposal.	Consistent with this change, the updated proposal amends the catchline of this section from “Timeline for review of human research proposals” to “Minor amendments to human research proposals.”	The department unintentionally omitted the amended catchline from its Virginia Regulatory Town Hall submission. The updated catchline will align with the regulatory amendments but will not change the provision’s substance, nor have an additional impact.
170-180	N/A	The current provision directs the HRRC to review all human research activities annually to ensure conformity with the director-approved proposals. At the Proposed Stage, the board expanded the provision to require these annual reviews for all ongoing activities, and not just human research proposals.	*The revised provision adds additional language to clarify that the scope of the annual review includes only those activities under the HRRC’s purview. The revisions also update the catchline to reflect the earlier proposed expansion.	The revised limiting language is intended to ensure that the HRRC is clear on which activities are subject to annual review. The change will clarify the initially proposed amendment, in turn, increasing the number of reviews the HRRC must conduct annually, but proposed changes will limit the increases. The change to the catchline is not expected to impact operations.
170-220	N/A	Initially, the proposal added language requiring the researcher to include with their formal final report a disclaimer that the department does not necessarily endorse the researcher’s conclusion. Under the proposal, the director could waive the disclaimer, in which case the	The revised proposal seeks an additional minor change to this section to clarify that in instances when the director waives the required statement, the regulated party must submit the relevant materials for the coordinator of external research’s review and approval.	The revised proposal is intended to clarify the initially proposed amendment and is not expected to have any additional operational impact.

		regulated party needed to submit the relevant materials to the coordinator of external research at least 30 days before the anticipated submission date.		
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Detail of All Changes Proposed in this Regulatory Action

List all changes proposed in this action and the rationale for the changes. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Put an asterisk next to any substantive changes.

Current chapter-section number	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of updated requirements
170-10	N/A	Definitions. Definitions for various terms, including the following, are provided in Section 10 of this chapter: aggregate data (<i>statistics relating to broad groups making it impossible to distinguish individual properties</i>); case-specific data (<i>nonaggregated data providing information about individuals in a group</i>); coordinator of external research (<i>director-designated DJJ employee who reviews research proposals and data requests in accordance with chapter</i>); de-identified data (<i>data with common identifiers removed to prevent others from determining the individual's identity</i>); external research (<i>research conducted at or using resources of entity owned, operated, or regulated by DJJ or the board by researchers outside the DJJ or who are not employees of another state agency conducting a legislative-mandated study</i>); human	The board is proposing amendments to the following terms and definitions: Coordinator of external research – *Amended to remove requirement that the coordinator review proposals in accordance with department procedures, as this provision may violate 1VAC7-10-140, which prevents agencies and boards from incorporating their own documents by reference except in unique and highly unusual circumstances. External research – Changed the terminology to “external research or evaluation project,” to capture fully the projects included under this term. Modified the definition to prevent non-DJJ employees or contractors who perform data analysis, quality or process improvement projects, or research for the department from conducting the project. Moved the exclusion for employees from other state agencies conducting a legislative-mandated study to Section 15. Clarified that data analysis, quality

	research (<i>systematic investigation including research development, testing, and evaluation using human subjects designed to develop or contribute to generalized knowledge, excluding research exempt from federal research regulation under 45 CFR 46.101(b)</i>); Human Research Review Committee/HRRC (<i>committee established to oversee human research proposals</i>); human subject (<i>individuals under care, custody, or supervision of DJJ or a board-regulated program or a family member who is proposed to be or is a subject of human research, including an individual employed in or providing contractual services to a JCC or other DJJ or board-regulated facility or program</i>); informed consent (<i>knowing and voluntary agreement without inducement or force, fraud, deceit, duress or other form of constraint or coercion of a person capable of exercising free choice. Definition sets out the five required elements necessary for informed consent</i>); internal committee (<i>DJJ committee established to oversee de-identified case-specific data</i>); legally authorized representative (<i>custodial parent, legal guardian, or other person authorized to consent to the individual's participation in human research on a prospective subject's behalf</i>); nontherapeutic research (<i>human research with no reasonable expectation of direct benefit to the human subject's condition</i>); organizational unit head (<i>person in charge of a JCC, CSU or other organizational unit of DJJ or board-regulated entity</i>); principal researcher (<i>person responsible for the research design, implementation, findings, and supervision of research staff</i>); research (<i>systematic development of knowledge</i>	improvement projects, and other research constitute external research or evaluation projects. Human research – Modified to exclude from the definition quality or process improvement projects and to correct an erroneous citation to a federal regulation. Principal researcher – Stricken and replaced with the term, “external project lead,” to denote individuals overseeing human research and data requests. Research – Amended to simplify the definition by explaining that research must contribute to generalizable knowledge, as set out in the Code of Federal Regulations' definition (45 CFR 46.102). Written – Amended term and definition to align more closely with the term and definition contained in § 1-257 of the Code of Virginia. The board proposes to add the following definitions for undefined terms used throughout this chapter or addressed in the updates: Data trust – Added to capture the Commonwealth Data Trust authorized in § 2.2-203.2:4 and the Virginia Workforce Data Trust authorized in § 2.2-2041, the secure environments DJJ has joined for purposes of sharing information with other members. External project lead - Added to replace the term, “principal researcher, as explained above. The definition excludes individuals employed by or contracted to perform research for the department. Quality or process improvement project – Added to describe the types of projects (the process for which is set out in a new § 125), that look for indicators of quality in a program with no intent of publishing or sharing
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		<i>essential to effective planning and rational decision making, the findings of which should provide valuable information for policy options);</i> research project <i>(systematic collection of information, analysis of data, and preparation of findings);</i> Virginia Longitudinal Data System/VLDS <i>(data system providing de-identified case-specific data from participating agencies through approval or denial by each sponsoring agency maintaining the data);</i> written <i>(communicated in writing in hard copy or electronic form).</i>	findings beyond the researcher and others at DJJ's discretion. The following terms and definitions were stricken due to the elimination of sections or provisions addressing the terms: aggregate data (§ 55), legally authorized representative (§ 80, 160), and nontherapeutic research (§ 80, 150). The term, "research project" was removed because it is used interchangeably with "research" in this chapter. Finally, minor amendments are made to simplify the following definitions: case-specific data, de-identified data, HRRC, human subject, informed consent, internal committee, organizational unit head, and VLDS.
N/A	170-15	N/A	Applicability. The proposal adds a new section that defines the scope of the chapter. Under this section, legislative-directed research or evaluation projects performed by staff from other state agencies are excluded. Currently, this language is contained in the definition of external research. The section also excludes requests for juvenile records and reports in accordance with § 16.1-300 from this chapter, as these requests are covered primarily under another chapter. These changes largely clarify existing practices and are not expected to have additional impacts.
N/A	170-17	N/A	Department requests for research; research conducted by state criminal justice agencies. A. The proposal adds a new section with subsection A addressing research conducted by external entities at the department's request in accordance with § 16.1-300 A 10. Because these proposals currently are not subject to this chapter, *the department proposed language to allow DJJ to apply a portion or all the chapter's requirements when asking an outside agency to research or evaluate the department. Historically, DJJ has addressed these types of requests on a case-by-case basis. This change will

			alert outside entities that they may be subject to this chapter. B. While § 15 excludes state criminal justice agencies requesting data under § 16.1-300 from this chapter's reach, the proposal still directs such agencies to fill out and submit the department's Data and Research Proposal and Confidentiality Agreement. This will help the department verify the entity is a state criminal justice agency, confirm that the requested information falls under § 16.1-300, and ensure that, upon receipt, the recipient will keep such information confidential. This change is intended to enhance compliance of other provisions by giving these entities clear guidance.
170-20	N/A	General requirements of external researchers. A) Requires principal researchers to have academic or professional standing or job-related experience in the field being studied or be supervised by such person. B) Lists the principal researcher's responsibilities for i) the research staff's conduct; ii) protecting the rights of project subjects; and iii) providing required information to the coordinator of external research, organizational unit heads, and the HRRC.	General requirements of external project leads. The proposal amends the catchline to refer to external project leads since this section addresses those parties. A) The proposal replaces all references to 'principal researcher' in this section with 'external project lead,' and *modifies this subsection so that the project lead can no longer serve in this capacity without the requisite qualifications, regardless of their supervisor's standing. This change operationalizes the department's current requirements, and no additional impact is expected. B) *The proposal removes the list of specific responsibilities borne by the external project lead, instead imposing a more general requirement that the project lead ensure all the chapter's applicable requirements are met. The change comports with DJJ's current approach and is not expected to have a significant impact.
170-30	N/A	Professional ethics. Requires all research to conform with standards of ethics of professional societies and provides a list of examples.	*The proposal repeals this provision as vague and unnecessary. Because the department does not base its decisions for data requests and research proposals on the entity's conformity with these standards, the change is not expected to have a significant impact.
170-40	N/A	Confidentiality requirements of all research. B) Requires the regulated community to keep all records and information given by research	B. The proposal removes limiting language suggesting that the confidentiality requirement is limited to protecting confidential information under § 16.1-300 of the Code. The

		subjects or DJJ employees confidential pursuant to § 16.1-300 of the Code and applicable rules and regulations regarding confidentiality of juvenile records. C) Provides that breaches in confidentiality will be sanctioned in accordance with applicable laws, regulations, policies, and procedures.	proposed language is unnecessarily restrictive in its failure to protect information on employees and others who meet the human subjects definition but are not covered under § 16.1-300 or other juvenile confidentiality provisions. The proposal removes these restrictive references to ensure that researchers will observe other applicable confidentiality laws. This change is consistent with the agency's current practices and will have no additional impact. Former C. The proposal strikes former subsection C entirely. The reference to policies and procedures is an impermissible violation of 1VAC7-10-140. The remaining language is duplicative of subsection B since applicable laws and regulations already dictate the sanctions resulting from confidentiality breaches. The department's existing guidance document does not outline additional sanctions apart from those set out in law and regulation; therefore, this change will have no additional impact.
170-50	N/A	Conditions for department approval of external research and data requests. Establishes various conditions necessary for the department to approve external research and data requests. Among them: 1) DJJ's resources must be sufficient to accommodate the request and the request's benefits justify DJJ's involvement, 2) the request may not interfere significantly with DJJ programs or operations, and 3) the request must be compatible with the juvenile justice system's goals and DJJ's organization.	*The proposal strikes the third condition based on its close resemblance to the first condition. This change is not expected to have a significant impact on which projects and requests are determined eligible for approval.
170-55	N/A	Review and approval of aggregate data requests. A-C). Sets out the process for department approval of aggregate data requests and the requirements to notify the principal researcher of the department's decision regarding the request within a specified timeframe.	*The proposal repeals this entire section to accomplish regulatory reduction. Aggregate data involves dating pertaining to broad classes or groups, and the department does not believe these provisions on processes for fulfilling such requests are necessary to interpret the law. Entities seeking such information need only submit a form available on the department's website. There is no need to regulate this area.

170-60	N/A	Formal agreement required. Prohibits the commencement of a case-specific data request or human research request until all reviews required in this chapter are completed and the principal researcher receives a copy of the Research Agreement signed by the DJJ director.	The proposal significantly restructures this section so that it provides additional clarity as to when the various forms currently addressed in this chapter must be submitted to initiate a research project or data request and so that provisions in the guidance document that impose requirements will be enforceable. The proposal also replaces the reference to the “Research Agreement” with the “Data and Research Agreement” and uses that term throughout the section. New A) The proposal adds this new subsection, requiring external case-specific data requests, research proposals, and *quality or process improvement project requests be initiated by completing and signing the Confidentiality Agreement, Data and Research Proposal, and Data and Research Agreement. While various individual provisions in the regulation include language requiring the submission of one of these forms, this change makes it clear that all three forms are required for these specified requests. Because this amendment establishes the submission requirements for the three forms, individual provisions elsewhere in the regulation requiring submission of or signatures on any individual form are stricken. This language is included in the current guidance document; therefore, beyond clarifying the process, the proposed amendment will have no additional impact. New B) *The proposal adds this new subsection to require the submission of the Confidentiality Agreement, Data and Research Proposal, and Data and Research Agreement only for those external case-specific data requests submitted through the VLDS or through a data trust if the department serves as the sponsoring agency for the VLDS request or its contribution to the data trust was not mandated by state law. New C) *The proposal adds a new subsection requiring the Confidentiality Agreement to be signed by every individual who may access the data. This language is included in the
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			current guidance document; therefore, this change will have no additional impact. New D and E). The proposal also adds these subsections specifying what information must be captured as part of the Data and Research Agreement and prohibiting the commencement of certain projects until the agreement has been completed and signed. Most of these requirements currently are set out in Section 65, which addresses only case-specific data requests. By moving these requirements to this section, the proposal clarifies that the required components of the Data and Research Agreement remain the same regardless of whether the agreement is submitted to initiate an applicable external data request, research project, or quality or process improvement project. In addition to rearranging the language in this manner, the proposal replaces the language, currently in § 65(a), which requires the Data and Research Agreement to specify when progress reports will be required, with new language in § 60 that directs the requester to agree to provide DJJ with annual progress reports along with any additional progress reports mandated and scheduled by DJJ.
170-65	N/A	External case-specific data requests. A) Requires submission of the Confidentiality Agreement, Research Proposal, and Research Agreement to DJJ to initiate external case-specific data requests. B) Requires the principal researcher's and, if applicable, student researcher's signature for Research Agreement submissions. C) Requires the coordinator of external research to determine that certain requirements are met within 10 business days of receiving the data request, including that: 1) the request meets the conditions for approval in §§ 30 and 50; 3) the principal researcher has the appropriate	A) The proposal strikes this subsection, as § 60 now includes more comprehensive coverage of these requirements. This reorganization will have no additional impact. B) The proposal strikes this subsection. Because clarifying language in the amended Section 60 requires submission through completion and all required signatures on all forms, this subsection is no longer necessary. This change will have no additional impact. Former C, new A). The proposal clarifies that the coordinator of external research must verify these requirements within 10 business days of receiving the completed forms, thus signifying that the 10-day clock does not start running if the submitted forms are not completed. This clarifying language eliminates the need for the

	standing or experience in the study area; 4) the proposal is in the required format and includes required information; and 7) DJJ has resources available to process the request. E. Allows the DJJ director to approve data releases that contain some otherwise sensitive identifiers enumerated in subsection D for research benefiting the department if the researcher agrees that the information will be kept confidential or released or published in aggregate form. H. Requires the director, once the coordinator of external research has determined that all the conditions for case-specific external data requests have been met, to designate an internal committee, which must meet within 20 business days. Among its activities, the committee must (2) determine that the research is beneficial to the department. J. Directs DJJ to notify the researcher of the director's decision on the data request within five business days of the decision and requires a written rationale for any denials, and the research agreement containing the director's signature for approved requests. This subsection also specifies the required components of the research agreement, which shall address: a) when progress reports are required, including a requirement to develop a schedule for such progress reports in consultation with the HRRC when the request involves human research; b) DJJ's unrestricted authority to use the research findings according to professional standards of research; c) the requirement to submit the final report to DJJ electronically; d) the requirement to submit all external documents from the data collected electronically to DJJ, including a	fourth condition that the proposal meet the format and information requirements; thus subdivision 4 is stricken. *The proposal also relieves the coordinator of external research of subdivision 1's mandate to verify the request meets the conditions of § 30, since that provision is proposed for repeal. This change may cause a minor reduction in the coordinator of external research's duties. The proposal also minimally modifies subdivision 3 by replacing the reference to the principal researcher with the external project lead. Finally, the proposal strikes subdivision 7 as duplicative since the adequacy of DJJ's resources to process the request must be considered under subdivision 1. This change will have no impact. New C) *The proposal adds a new subsection authorizing the department to consider additional identifiers as sensitive, and in such cases requiring removal of such information from the data set. These identifiers include (i) dates relevant to the juvenile's offenses, programming, or placements, (ii) location information more specific than the locality, state, and zip code; (iii) record numbers; and (iv) other combinations a reasonable person could use to determine an individual's identity. While the guidance document supplementing this regulation already allows the department to consider the identifiers in (i) through (iii) as sensitive, this change will make those provisions enforceable. The proposal's additional catchall provision will allow other field combinations to be considered sensitive if a reasonable person could identify the individuals based on the information. This adds an additional layer of protection to ensure identifying information is not released. Former E, new D) *The proposal adds clarifying language that restricts the director's authority to release data, on a case-by-case basis, containing a limited number of otherwise sensitive data unless providing such data does not violate any confidentiality provisions in Title 16.1. This is intended to clarify the current process
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		disclaimer that the findings are the researchers' responsibility and that DJJ's cooperation should not be construed as an endorsement of the findings. The director or designee may waive this statement; and e) the research agreement is not effective until signed by the principal researcher and director. K. Directs the department to provide a final copy of the research agreement containing the director's signature to the researcher via first class mail, email, or fax. L. Exempts external case-specific data requests submitted through the VLDS from this section's requirements and subjects them to 6VAC35-170-67.	and ensure that any DJJ director will release such information only within the confines of the confidentiality requirements in Title 16.1. Former H, new G) *The proposal removes the provision requiring the internal committee to convene within 20 business days of receiving the external case-specific data proposal. Historically, the department has had challenges aligning the internal committee's schedules to satisfy this requirement. The proposed change will allow the committee to continue its routinely scheduled quarterly meetings without having to plan additional meetings or to meet at other intervals. *The proposal also expands the duties of the internal committee by requiring them to verify the request meets Section 50's conditions for DJJ approval of research. Because Section 50 allows the department to approve external data and research requests only when their benefits justify DJJ's involvement, the proposal also strikes former subdivision 2, requiring the internal committee to determine the research benefits the department. Former J) The proposal moves the required components of the research agreement to Section 60. Because the scope of Section 60 extends beyond external research requests, the proposal eliminates the language mandating that the schedule of progress reports for external research requests be developed in consultation with the HRRC. Former J, New I) The proposal clarifies that the five-day deadline for notifying the researcher of the director's decision on the request commences once the department (e.g., the Research Unit) receives the director's decision. *The proposal also removes the provision requiring the department to provide a written rationale if the director denies the request. While DJJ likely will continue this practice, it does not require regulation. Former K, current I) The proposal removes this subsection entirely and adds language in the revised subsection I reflecting the
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			department's practice of emailing the Research Agreement. Former L, new J.) *The proposal modifies this provision to clarify that the process for external case-specific data requests set out in this section only applies to requests submitted through the VLDS if DJJ will serve as the sponsoring agency. *The proposal exempts requests submitted through a data trust portal if DJJ's contribution to the trust was mandated by state law. All requests submitted through the VLDS or a data trust portal also will be subject to Section 67 regardless of the sponsoring agency or whether DJJ's data contribution was statutorily mandated. Finally, the proposal expands this section so that its provisions apply to data requesters and researchers. This is a clarifying change that will have no additional impact. Similarly, the proposal makes numerous additional technical changes for clarity, none of which is expected to have additional impact.
170-67	N/A	VLDS requests. A) Requires requests for external case-specific data submitted through the VLDS to use the VLDS portal. B) Requires researchers to comply with all VLDS procedures in accessing VLDS data. C) Sets the following restrictions on the HRRC chair's ability to approve requests submitted through the VLDS or data trust portals: The request: 1) must satisfy § 50's conditions for DJJ approval of research, 2) may not be a human research proposal and may not require HRRC review, 3) must be in the required format and include all required information, 4) must comply with basic research standards and applicable laws, and 5) must be limited to data accessible and available in the VLDS. D. Allows the chair of the HRRC to restrict the scope of data for requests submitted through the VLDS portals if the data	Requests submitted through the VLDS or a data trust. The proposal replaces the current catchline to reflect the inclusion of data trusts. A) The proposal strikes subsection A entirely due to its instructional nature. As there is no other practical means of submitting such requests, this change will have no additional impact. B. The proposal strikes subsection B entirely on the basis that compliance with VLDS procedures need not be regulated by the department. Researchers and requesters must comply with VLDS procedures to access the portal; thus, this change may have no practical impact. C. The proposal removes former subdivisions (C)(1)-(C)(3) and (C)(5), based on the following concerns: • (C)(1) - Section 30 has been repealed, and Section 50 does not apply to VLDS requests because the data is already in the portal. • (C)(2) – These scenarios are not likely for VLDS requests and, therefore, need not be addressed. • (C)(3) -The requirement for full completion of the required forms is

		requested are unrelated to the purpose of the research study.	embedded in Section 60 and does not require repeating. • (C)(5) – Researchers will be subject to this requirement as part of the process for accessing information in the portal; thus, a regulatory requirement to this effect is not necessary. *The proposal adds a new subdivision (C)(1) requiring the research aim and requested data be appropriate in content and scope, and a new subdivision (C)(3) mandating that the requester agree to provide DJJ with annual progress reports and a final report of its findings, including goals for improvement and an actionable plan for implementing changes. These changes are consistent with DJJ's current practices and are not expected to impose additional burdens or significantly change the process. Former D.) The proposal strikes subsection D entirely, as the proposed subdivision (C)(1) eliminates the need for this provision. This change is not expected to have additional impact.
170-69	N/A	Minor amendments to data requests. Allows for an expedited review of a researcher's minor amendments to an external data request the DJJ director has approved if the amendment does not alter the scope of the request.	The proposal makes minor amendments to this provision to change the individual making the request from the researcher to the data requester and to clarify that expedited reviews are permissible only for nonsubstantive amendments. The proposal also requires the HRRC's expedited review to occur in writing. These changes, as well as other technical changes, are intended to clarify the current process and will have no additional impact.
170-70	N/A	Requirements specific to human research. C) Provides that incentives for research participation are discouraged but not prohibited. Incentives must be appropriate to the custodial status of the juvenile and proportionate to their situation. E. Prohibits researchers from conducting human research without approval of the HRRC.	C) *The proposal modifies this provision to remove the language indicating that incentives are discouraged. This is not reflective of the department's practices. The department understands that soliciting participation in research can be challenging even when incentives are offered. Therefore, the proposal continues to allow incentives, in accordance with the limitations in subsection C. E) The proposal modifies this requirement to prohibit such research without the review and approval of the

			HRRC. This language aligns with the language in § 32.1-162.17 regarding the HRRC's review and approval of the project. This change is intended to clarify current requirements and will have no additional impact. *The proposal also requires department review before human research may be conducted. This is consistent with the department's current practices, as set out in the guidance document, and will have no additional impact. New F) *The proposal adds a new subsection to reflect language in the supplemental guidance requiring endorsement from an Institutional Review Board for human research that is not exempted by § 32.1-162.17 of the Code. As this is consistent with DJJ's current practices, the change will have no additional impact. The proposal makes additional inconsequential, technical edits.
170-80	N/A	Informed consent required for human research. Enumerates in subsections A) through H) all the requirements for obtaining informed consent from a human subject prior to conducting human research as articulated in § 32.1-162.18. Note that subsection B requires informed consent to be given in writing and witnessed for any human subject who is competent.	The current regulatory provision is very similar to the statute with some minor differences. Subsection B of the regulation uses "competent" and "incompetent" terminology, reflecting the statutory language before 2003 legislation replaced the language with "capable" or "incapable" "of making an informed decision." A couple other provisions in the statute pertaining to therapeutic treatment of individuals with neurodegenerative diseases and human research protocols contrary to the prospective subject's religious beliefs or values are not addressed in the regulation. Beyond the differences addressed above, the remaining statutory provisions are duplicated in the regulation. To eliminate this duplication, the proposal replaces the regulation's specific requirements with general language directing researchers to obtain informed consent in accordance with § 32.1-162.18 before conducting human research. This approach is consistent with guidance provided in ORM's Regulatory Reduction Manual instructing agencies to cite the specific statute rather than mirroring the statute in a regulatory provision. The change also eliminates the discrepancies discussed above.

			Because researchers are currently subject to the state statutory provision, the department does not expect these changes to have an additional impact.
170-90	N/A	Exemptions from the requirements governing human research. Establishes the categories of human research that are exempt from the human research process in accordance with § 32.1-162.17, are not subject to this chapter, and must comply with DJJ's separate nonhuman research review process. The provision also highlights the categories of human research subject to this chapter by virtue of 45 CFR 46.104 (i.e., research on certain involuntarily incarcerated individuals and research on certain children who have not attained 18 years of age.	The proposal replaces the categories of human subjects individually identified as exempt in accordance with § 32.1-162.17 of the Code with a reference to the statute. This approach is consistent with ORM's guidance. These nonsubstantive amendments will have no operational impact. In accordance with 45 CFR 46.104, however, certain categories of human research remain subject to this chapter. The proposal retains this language in subsections B and C.
170-100	N/A	Proposal for external research. B. Requires the principal researcher to submit to the coordinator of external research the complete research proposal, which shall include, among other information, the principal researcher's name, address, telephone number, email address, title, and affiliation, as well as the name, telephone number, and email address of any person coordinating the project who is not the principal researcher.	A-B.) The proposal replaces references to the "principal researcher" with the "external project lead" in subsections A and B and "the research proposal" with the "Data and Research Proposal" in subsection B to conform to changes elsewhere in the chapter. These nonsubstantive changes will have no additional impact. B. The proposal strikes language mandating that the Data and Research Proposal be submitted to the coordinator of external research, as the submission requirements are now set out in the amended Section 60. This nonsubstantive change will have no impact. Additionally, the proposal replaces the requirement in subdivision 1 that the research proposal capture the principal researcher's address, email address, and telephone number, with a more general requirement that it include the individual's contact information. This will give DJJ greater flexibility in what contact information it seeks from researchers as that category of information evolves. These changes are not expected to have significant additional impact. *The proposal also adds language requiring the research proposal to include the external project lead and

			student's resume or curriculum vitae, if applicable. New C) The proposal adds a new subsection requiring the coordinator of external research to verify the proposal's compliance with basic research standards and applicable laws. As this language is currently contained in Section 110, the change will have no additional impact.
170-110	N/A	Initial review by coordinator of external research. Sets out the process for the coordinator of external research's initial review of research proposals, which involves: 1) verifying the proposals are in the required format and contain all required information; 2) confirming the proposal's compliance with basic research standards and applicable laws and 3) sending the proposals to the appropriate DJJ personnel (and the HRRC for human research) for review.	The proposal repeals this provision. Subdivision 1 is unnecessary because the review and requirements regarding format and information are captured elsewhere in the chapter, and the provision is more instructional in nature. Similarly, subdivision 3 is instructional in nature and need not be regulated. This leaves subdivision 2, which can be combined with the requirements in Section 100; therefore, the department proposes moving subdivision 2 into subsection C of Section 100, thereby enabling the repeal of this entire section. These changes will have no additional impact.
N/A	170-125	N/A	Quality or process improvement projects: *The proposal adds a new section establishing a process for considering quality or process improvement project requests. Historically, the department has considered these requests outside the regulation and associated guidance document. The department's reviews and determinations have been conducted on a case-by-case basis and have lacked consistency. The proposal establishes definitive rules and conditions that provide a streamlined and consistent process for project submission and review.
170-130	N/A	Human Research Review Committee. A. Requires DJJ to establish an HRRC with members from varied backgrounds and prohibits their direct involvement in the proposed human research or administrative approval over such research except in connection with their HRRC position. C. Allows the HRRC to require additional information from the	A. As much of the language in this subsection duplicates § 32.1-162.19 A of the Code, the proposal replaces this specific language with a requirement that DJJ establish an HRRC in accordance with the statute. This is consistent with guidance from ORM and will have no additional impact. C. The proposal strikes subsection C as unnecessary. The HRRC's requests generally are limited to information already mandated in this chapter;

		researcher before making a recommendation to the director.	therefore, removing this provision will have no additional impact.
170-140	N/A	Timeline for review of human research proposals. A) Sets the deadline for the HRRC to review human research proposals to a maximum of 30 business days after receiving the completed proposal. B) Allows the HRRC to expedite its review of a human research proposal on the researcher's request if the research presents no more than minimal risk to the human subjects and either another agency's HRRC has reviewed and approved the proposal or it proposes only minor changes to previously approved research.	Minor amendments to human research proposals: The proposal amends the catchline to more closely reflect the existing and proposed provisions' focus on the process for amending human research proposals. Former A) *The proposal strikes this provision entirely. As with the internal committee, coordinating the schedules of the HRRC to ensure this required deadline is met has presented challenges. This change aligns with the change proposed for internal committees in Section 65. The change will allow the department greater flexibility in scheduling the HRRC meetings and reviewing the proposals. New A.) *The proposal directs the HRRC chair to approve the request for an expedited review in writing, clarifies that the changes must occur during the approved project period, and eliminates a researcher's ability to request an expedited review based solely on another agency HRRC's approval. Because other agencies' requirements for their HRRCs may differ, the department has been reluctant to expedite their reviews based on this approval. New B, Former C.) The proposal makes changes to former subsection C for style and clarity. These changes will have no additional impact.
170-150	N/A	HRRC review of human research proposals. Requires HRRCs reviewing human research proposals to consider the potential benefits and risks to human subjects and precludes the HRRC from recommending approval unless eight specified preconditions, originating from § 32.1-162.19 B of the Code, are satisfied.	Because the factors listed in § 32.1-162.19 B require mere consideration from the HRRC and are not conditions for approval, the current regulatory language is more restrictive than the statute. *The proposal removes the regulatory language identifying these specific preconditions and mandates that the HRRC consider each element outlined in § 32.1-162.19 B. This change aligns the regulation with the statutory requirement and is not expected to modify DJJ's practices in approving human research.
170-160	N/A	HRRC review of informed consent provisions (B and C.) Currently allows the HRRC to approve a consent procedure omitting or changing	(B and C.) Because the specific regulatory requirements for approving a consent procedure that amends or waives the informed consent elements is nearly identical to the statutory

		the basic informed consent elements or waiving the requirements to get informed consent if certain specified requirements are met and compliance with the requirements is documented.	conditions, the proposal replaces the specified conditions with a mandate that the HRRC comply with § 32.1-162.18 D's requirements to find and document the existence of certain conditions when it seeks to modify informed consent requirements and that it comply with § 32.1-162.18 E when it seeks to waive the requirement to obtain informed consent. The only difference is that the regulatory language empowers the HRRC, when it exercises the option to waive informed consent, to require that researchers give a written statement explaining the research to the legally authorized representative , as well as the human subject. Changing the provision so that it requires compliance with the statute means that the HRRC will no longer be empowered to mandate that researchers provide such information to the legally authorized representative.
170-170	N/A	Recommendation to director and final action. A) Upon review of the proposal, gives the HRRC the option to recommend approving, denying, or conditionally approving the proposed human research. C-D.) Requires the coordinator of external research to send a copy of the signed Research Agreement to the principal researcher once the director signs off, and, in any event, to notify the principal researcher of the director's final decision.	A) *The proposal modifies the third option to mirror the language in the associated guidance document, which allows the HRRC the alternative of deferring a recommendation pending receipt of additional information or modification of the proposal. While broader than the HRRC's option to recommend conditional approval under the current regulation, the change is intended to clarify current practices and will have no additional impact. C and former D.) *The proposal requires notification of the director's final decision within five business days of receiving the decision. This change is consistent with language already contained in the guidance document and will have no additional impact. The proposal makes additional style changes to align with the new form name and to streamline the language.
170-180	N/A	Annual review of human research activities. Directs the HRRC to review all human research activities at least annually to ensure they conform with the proposal approved by the DJJ director.	Annual review of human research and other activities. *The proposal expands the provision's scope so that the HRRC will need to review all ongoing activities within its purview, and not just human research activities. The amendments may increase the number of reviews the HRRC must conduct annually.

			Additionally, the proposal modifies the catchline to reflect the expanded scope of the provision.
170-185	N/A	Researcher noncompliance. A) Requires researchers to report noncompliance with the approved research proposal to the HRRC and the institutional review board. B) Enumerates the HRRC's options if it determines the research activities are not compliant with the approved proposal, state law, or regulations	A) The proposal replaces the researcher with the external project lead as the individual responsible for reporting noncompliance, which will clarify duties. New B) *The proposal adds a new subsection B directing the external project lead to report protocol violations to the coordinator of external research within five business days of becoming aware of the violation. This change is needed to enforce a requirement in the guidance document. Because this new language aligns with DJJ's current practices, the change is not expected to have an additional impact. The proposal makes other changes for style, all of which will have no substantive impact. New C, former B) The proposal makes a minor change to former subsection B to clarify that the HRRC can take any or all enumerated actions to respond to the noncompliance. This change is consistent with DJJ's current practices and will have no additional impact. Additionally, the proposal makes a minor change for style purposes.
170-190	N/A	Committee reports required. A. Requires the HRRC to submit annual reports on human research projects approved by the HRRC and the status of the project to the Governor, the General Assembly, and the director in accordance with § 66-10.1 of the Code. C. Directs the HRRC to ensure an overview of this report is posted on DJJ's website unless FOIA provides for an exemption.	A. The proposal clarifies that this requirement is applicable to human research projects that are reviewed and approved by the HRRC. This change is consistent with the language in § 66-10.1 and with DJJ's current practices. C. The proposal strikes subsection C and moves its requirements to a new subdivision 2 of subsection A. This formatting change is intended to demonstrate that the requirement is mandated in state law in § 32.1-162.19 and will have no additional impact.
170-200	N/A	Progress reports A. Allows DJJ to require periodic reports on the progress of research projects and imposes upon the principal researcher the duty to provide timely reports and supplementary information upon DJJ's request. B. Requires the researcher to submit annual progress reports	A-B.) The proposal modifies the language to direct the external project lead to provide annual progress reports summarizing progress with pending research, as well as timely provide whatever additional periodic reports or supplementary information DJJ requires. Because of these modifications, the proposal strikes the former subsection B, which change will

		when the research is not completed within one year of approval.	not modify the process for completing progress reports. New B.) The proposal adds language giving the director discretion to reconsider, reassess, or rescind an approval based on the progress report or the entity's failure to file a timely progress report.
170-210	N/A	Department permission to use research findings. Requires the research agreement to give the department unrestricted permission to use data, summaries, charts, graphs, or other illustrations resulting from the research project.	The proposal repeals this provision as unnecessary. The department believes it has this authority even absent an enabling provision to this effect in the Research Agreement. This change is not expected to have a significant impact on the process for reviewing and approving requests.
170-220	N/A	Final report. A) Provides that DJJ may require up to 10 copies of the formal final report that must be submitted to the coordinator of external research. B) Requires that the report contain a disclaimer, unless waived by the director, that the department's cooperation not be construed as endorsement of the research conclusions.	Research findings. Because the proposal seeks to expand this section's requirements to address external articles, reports, presentations, and publications generated from research, the proposal changes the catchline. A) *The proposal removes the outdated language allowing DJJ to require up to 10 report copies. Reports and other material generated from the research are submitted electronically, eliminating the need for multiple manual copies and for this language. This change will have no additional impact. B. *The proposal expands this subsection so that the requirement for the disclaimer also pertains to external articles, reports, presentations, and publications generated from the data and research. *The proposal gives the director the authority to waive the required statement, and in such instances, requires the material be submitted to the coordinator of external research for review and approval at least 30 days before the anticipated submission date. *The proposal also adds a deadline for electronically submitting the articles, reports, presentation, publications, and the final report to the coordinator of external research. These changes are consistent with requirements in the supplemental guidance document and will have no additional impact.
170-230	N/A	Written procedures	A) *The proposal strikes subsection A as unnecessary. DJJ may provide

		A) Directs the department to establish written procedures on the process for getting the organizational unit head's endorsement for external research proposals. B. Grants DJJ permission to establish written procedures outlining additional requirements for submitting, reviewing, and approving research projects and data requests and authorizing such procedures to identify additional sensitive data elements.	guidance on this process as a best practice but does not believe this area needs to be regulated. B) The proposal modifies this language to allow DJJ to provide guidance, rather than written procedures, for this process and strikes the language that allows such procedures to identify additional data elements. This language is no longer necessary given the newly added provision in Section 65 C, which grants DJJ the authority to consider "any other combination of fields that would enable a reasonable person to identify individuals, as sensitive data." This change is not expected to impact operations. The proposal makes additional minor changes for clarification.
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