



**Department of Juvenile Justice
Administrative Procedure**

Administrative Procedure # VOL I – 1.4 – 01	Statutory Authority: Title 66 of the <u>Code of Virginia</u>
Subject: Review and Approval of Data Requests and Research Proposals	Regulations: 6VAC-35-170 Minimum Standards for Research Involving Human Subjects or Records of the Department of Juvenile Justice
	ACA # 4-JCF-6F-05

I. PURPOSE

This procedure provides the process for the review and approval of three types of external data requests and research proposals. These are (1) external aggregate data requests, (2) external case-specific data requests, and (3) human research proposals.

This procedure implements and must be applied in conjunction with the Minimum Standards for Research Involving Human Subjects or Records of the Department of Juvenile Justice (6 VAC 35-170) issued by the Board of Juvenile Justice.

All research activities conducted within Virginia's juvenile justice system shall comply with all applicable state and Federal laws and regulations and with medical, societal, and professional ethics; guarantee the safety, health, privacy, and confidentiality of clients and staff; and prohibit unauthorized access to and publication of information that identifies individuals or families. Research activities must not impede rehabilitation and treatment of juveniles and must not compromise the security of juvenile facilities or place the public safety at risk.

II. SCOPE

This Directive describes how research proposals will be reviewed, approved, and coordinated. It does not apply to program evaluations, management studies and routine data analyses conducted or contracted for by the Department of Juvenile Justice (DJJ) or via a memorandum of agreement.

The Department may charge researchers reasonable fees to offset costs incurred in supporting specific research projects.

III. DEFINITION

This procedure uses terms as defined in the Minimum Standards for Research Involving Human Subjects or Records of the Department of Juvenile Justice in the Virginia Administrative Code or in § 32.1-162.16 of the *Code of Virginia*. Additionally, terms not defined in the *Code* are defined here, and shall have the meaning indicated, unless the context clearly demands a different understanding of the term.

Aggregate Data - Statistics which relate to broad classes, groups, or categories, so that it is not possible to distinguish the properties of individuals within those classes, groups, or categories.

Case-specific Data - Non-aggregated data that provides information about individuals within a group.

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Coordinator of External Research - The Department employee designated by the Director to receive research proposals from external entities and ensure the proposals are reviewed in accordance with the applicable administrative regulations and related department procedures. The Research Supervisor in the Legislative and Research Section is hereby designated as the Coordinator of External Research.

De-identified Data - Data with common identifiers such as names, phone numbers, social security numbers, addresses, etc. removed in order to eliminate the ability of an individual viewing the data to determine the identity of an individual.

Department - The Department of Juvenile Justice.

Director - The Director of the Department of Juvenile Justice or his designee.

Encrypted - The transformation of data through the use of an algorithmic process into a form in which there is a low probability of assigning meaning without the use of a confidential process or key, or the securing of the information by another method that renders the data elements unreadable or unusable.

External Research - Research conducted at or using the resources of a facility, program, or organization that is owned, operated, or regulated by the Department by researchers who are not part of the Department or under contract to the Department, or who are not employees of another state agency conducting a study at the direction of the General Assembly.

Human Research - Any systematic investigation, including research development, testing and evaluation, utilizing human subjects, that is designed to develop or contribute to generalized knowledge.

Human Subject - Any individual who is under the department's care, custody, or supervision, or a member of the family of such an individual, or an employee of the Department, who is or who is proposed to be a subject of human research.

Human Research Review Committee (HRRC) - The committee established by the Department to oversee human research proposals and activities in accordance with 6VAC35-170-130 of the Virginia Administrative Code and § 32.1-162.19 of the *Code of Virginia*.

Informed Consent - The knowing and voluntary agreement, without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion, of a person who is capable of exercising free power of choice.

Minimal Risk - The risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Nontherapeutic Research - Human research in which there is no reasonable expectation of direct benefit to the physical or mental condition of the human subject.

Organizational Unit - Central office, juvenile correctional centers, court service units, or other organizational unit of the Department.

Principal Researcher - The individual who is responsible for the research design, the conduct of research, supervision of research staff, and the research findings.

IV. PROCEDURES

A. External Aggregate Data Requests

1. External aggregate data requests will be submitted to the Legislative and Research Manager or designee via a detailed email outlining the specific information requested.
2. The Legislative and Research Manager or designee will determine the following:
 - a. If the data requested is accessible;
 - b. An estimate of the time required to process the data request; and
 - c. Based on staff workload, if staff resources are available to process the data request.
3. The Legislative and Research Manager or designee may approve and coordinate the provision of data. The Legislative and Research Manager or designee will notify the requestor of the approval or denial of the data request within 20 business days of receiving the request.

B. General Requirements for External Case-Specific Data Requests and Human Research Proposals

1. External data requestors, external researchers, and Department personnel proposing to conduct human research will follow the same steps in submitting their proposal for consideration by the Department. If a project involves both an external data request and a research proposal, the process for approving a research proposal will be followed to approve the project as a whole.
2. The Department's website will include information on requesting data and conducting research at the Department, including instructions and forms for use by external data requestors and researchers.
3. External data requestors and researchers to whom juvenile record information is disclosed will not redisclose or otherwise reveal the juvenile record information of an individual, beyond the purpose for which such disclosure was made. The prohibition on redisclosure shall not prevent publishing research findings based on juvenile information, provided the findings are presented using aggregate data or data from which individually identifying information has been removed, encoded, or encrypted.
4. External case-specific data requests and research proposals will be submitted to the Coordinator of External Research via the Research Proposal form, the Research Agreement form, the Confidentiality form, and any required attachments. The Research Agreement form must be signed by the Principal Researcher(s) and the Student Researcher (if applicable) at the time of submission. A Confidentiality form must be signed by every individual who may access the data.
5. The Principal Researcher will provide the Coordinator of External Research an electronic copy of the forms via email. In accordance with 6 VAC 35-170-100 (B), the research proposal should contain the following elements, as applicable to the research proposal:
 - a. Name, address, telephone numbers, title, and affiliation of the Principal Researcher;
 - b. Name of the person who will immediately supervise the project, if different from the Principal Researcher;
 - c. Funding source, if any;
 - d. Date of the proposal's submission to the Department;

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- e. Title or descriptive name of the proposed project;
 - f. Statement of the specific purpose(s) of the proposed project with anticipated results, including benefit to the Department;
 - g. A concise description of the research design and techniques for data collection and analysis and of the likely effects of the methodology on existing programs and institutional operations;
 - h. Time frames indicating proposed beginning and ending dates for data collection, analysis, preliminary report, and final report;
 - i. A listing of any resources the researcher will require from the Department or its units, such as staff, supplies, materials, equipment, work spaces, or access to clients and files;
 - j. Identification of the organizational unit where the research will be conducted and letter of support acknowledging the organizational units agreement to participate in research related activities, if applicable;
 - k. For student research, endorsement from the Researcher's academic advisor or other appropriate persons;
 - l. For research involving records of juveniles at state and local court service units, endorsement from the appropriate juvenile and domestic relations judge(s);
 - m. For human research, endorsement from the Institutional Review Board (IRB) of the institution or organization with which the researcher is affiliated (NOTE: There are additional requirements for human research detailed in this procedure.); and
 - n. A signed and dated statement that the Principal Researcher and the research staff have read and understand the Research Agreement.
6. Industry standard levels of encryption shall be required to protect all juvenile record information provided to researchers.
 7. The Principal Researcher must comply with the research plan as stated in the Research Proposal form, including the plan for disseminating findings. Any changes must be requested and approved before taking place.
 8. The Coordinator of External Research will distribute the findings of all external research projects to appropriate personnel and units in the Department. If the research findings have wider application outside the Department, the Coordinator of External Research shall consult with management to determine if and how to distribute the findings outside the Department.

C. External Case-Specific Data Requests

1. The following identifiers will be removed from the data unless otherwise approved. The dissemination of data containing a limited number of the listed identifiers may be approved for research benefiting the Department. If the fields requested by a researcher are such that a reasonable person could identify the research participants, the human research review process must be followed.
 - a. Names;
 - b. Dates (Date of birth, date of admission, date of release, etc.);
 - c. Postal address information, other than town or city, state, and zip code;
 - d. Telephone numbers;
 - e. Social security numbers;
 - f. Medical record numbers;
 - g. Account numbers (Juvenile Tracking System, Direct Care, etc.);
 - h. Biometric identifiers, including finger and voice prints; and

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- i. Full face photographic images and any comparable images.
2. Within 10 business days of receiving the data request, the Coordinator of External Research will determine the following:
 - a. The request is in the required format and includes all required information;
 - b. The data requested is accessible; and
 - c. An estimate of the time required to compile the data request.
3. The Legislative and Research Manager will assess staff workload and resources and determine if staff and resources are available to process the data request, as required.
4. Upon the determination that staff and resources are available to process the data request, a committee with members designated by the Legislative and Research Manager, with the Legislative and Research Manager serving as Chair, shall act on a research proposal within 20 business days. The Committee may meet in person, conference call, or via email. The Committee will:
 - a. Review the data requested and determine if it is necessary to restrict the scope of the information provided. The scope of information may be restricted for any reason.
 - b. Determine if the project is beneficial to the Department.
 - c. Ensure juvenile confidential information will be adequately protected.
 - d. Make a recommendation to the Department Director or his designee to approve or deny the request. The Director hereby designates the authority to approve or deny external case-specific requests to the Director of Policy and Planning.
5. The Coordinator of External Research will submit the Research Proposal; the Research Agreement, signed by the researcher; and the Committee's recommendation to the Director of Policy and Planning for review.
6. The Director of Policy and Planning will approve or deny the proposal within 10 business days of receiving the recommendation and will communicate the approval or denial to the Legislative and Research Manager and the Coordinator of External Research.
7. Within five business days of receiving the decision of the Director of Policy and Planning, the Coordinator of External Research shall:
 - a. Notify the researcher that the proposal was not approved; or
 - b. If the research proposal is approved, send the signed Research Agreement to the Principal Researcher. The Research Agreement will outline the respective responsibilities of the parties and will specify:
 - 1) When progress reports shall be required, if applicable;
 - 2) The Department shall have unrestricted permission to use the research findings in accordance with professional standards of research;
 - 3) A final report shall be submitted electronically to the Coordinator of External Research;
 - 4) All external articles, reports, and presentations made from the data shall be submitted electronically to the Coordinator of External Research and shall include the statement, "The findings of this study are the responsibility of the researchers, and cooperation by the Virginia Department of Juvenile Justice in facilitating this research should not be construed as an endorsement of the conclusions drawn by the researchers;" and

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- 5) The Research Agreement is not effective until signed by both the Principal Researcher and the Director of Policy and Planning.
8. The following process shall be followed to request and approve a modification to an approved project:
 - a. The Principal Researcher shall submit a red line version (e.g., Track Changes) and clean version of the modified Research Proposal form via email to the Coordinator of External Research.
 - b. Within 10 business days of receiving the research proposal, the Coordinator of External Research will consult with the Legislative and Research Manager to determine if the requested modifications substantively change the criteria considered in the original review. If so, full review is required and shall follow the process described above for new proposals. If not, the Legislative and Research Manager may approve the modifications under expedited review. The Coordinator of External Research shall notify the Principal Researcher of the decision.

D. Human Research General Provisions

1. The categories of human research listed in *Code of Virginia* § 32.1-162.17 are exempt from the provisions in this procedure.
2. Human research that is not exempted by *Code of Virginia* § 32.1-162.17 requires endorsement from the (IRB) of the institution or organization with which the researcher is affiliated.
3. No human research project may be undertaken within the Department of Juvenile Justice without the express, written authorization of the Department Director upon the recommendation of the Human Research Review Committee.

E. Human Research Review Committee

1. To ensure the competent, complete, and professional review of human research activities, there is hereby established a Human Research Review Committee as required by *Virginia Code* § 32.1-162.19. The Legislative and Research Manager shall keep a current listing of members of the Human Research Review Committee.
2. The Human Research Review Committee shall consist of at least seven persons representing varied backgrounds, including:
 - a. The Legislative and Research Manager, who will serve as chair of the Committee;
 - b. The Chief Psychologist of the Department's Behavioral Services Unit;
 - c. At least three persons who are not employed by the Department;
 - d. At least one person from a non-scientific profession (e.g., lawyer, ethicist, clergy person); and
 - e. At least one person with the background and experience to advocate for the welfare of human research subjects.
3. Committee Operation
 - a. The Committee will meet as often as necessary to give timely consideration to human research proposals. Whenever practicable, proposals will be emailed to the Committee members, who shall act on a research proposal within 30 business days of receipt.

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- b. A Committee member who is directly involved in a research project or has administrative authority over a research project apart from his or her role on the Committee shall not vote on such research.
- c. A simple majority of Committee members will constitute a quorum. The Committee may meet in person, conference call, or via email.
- d. The Committee may consult with any person who has expertise or competence pertinent to the proposed research. Such persons may offer their opinions but may not vote when the Committee makes its decision.

F. Review of Human Research Proposals

1. Within 10 business days of receiving the research proposal, the Coordinator of External Research will determine the following:
 - a. The proposal is in the required format and includes all required information;
 - b. The Principal Researcher has appropriate academic or professional standing or job-related experience in the area to be studied, or is directly supervised by a person with such standing or experience;
 - c. The research conforms to generally accepted ethical standards of professional societies such as the American Correctional Association, the American Psychological Association, the American Sociological Association, the National Association of Social Workers, the American Evaluation Association, or their equivalent;
 - d. The proposal complies with basic research standards and applicable laws;
 - e. The proposal supports the mission and goals of the Department;
 - f. The proposal could reasonably comply with the criteria to be examined by the Committee;
 - g. The data requested is accessible, if applicable; and
 - h. An estimate of the time required to compile the data request, if applicable.
2. The Legislative and Research Manager will assess staff workload and resources and determine if staff and resources are available to process the data request, as required.
3. If the Coordinator of External Research, after consultation with the Legislative and Research Manager, determines that these criteria cannot be satisfied through reasonable modifications to the proposal, the proposal will be denied and written notification sent to the Principal Researcher.
4. If the proposal is not denied, the Coordinator of External Research will notify the Principal Researcher of any necessary changes, additional information, or clarifications.
5. Within 10 business days of receiving a research proposal that complies with all criteria considered by the Coordinator of External Researcher, the proposal will be distributed via email to the Committee.
6. The Committee will review the proposal within 30 business days and make a recommendation to the Department Director.
7. In reviewing a human research proposal, the Committee must determine that the proposal meets the following conditions set forth in 6 VACV 35-170-50:
 - a. The Department has sufficient financial resources and staff to support the research project, and that on balance the benefits of the research justify the Department's involvement;

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- b. The proposed research will not interfere significantly with Department programs or operations, particularly those of the operating units that would participate in the proposed research; and
 - c. The proposed research is compatible with the purposes and goals of the juvenile justice system and with the Department's organization, operations, and resources.
8. In reviewing a human research proposal, the Committee will also consider, as required by *Code of Virginia* § 32.1-162.19, if:
 - a. The research's potential risks and benefits are adequately described;
 - b. The methodology of the research is adequate;
 - c. The research, if it is nontherapeutic, presents more than a minimal risk to the human subjects;
 - d. The rights and welfare of the human subjects are adequately protected;
 - e. The potential benefits to the human subjects outweigh the risks to them;
 - f. The researchers are appropriately competent and qualified;
 - g. The criteria for selecting subjects are valid and equitable; and
 - h. Informed consent will be obtained by methods that are adequate, appropriate, and in accordance with the requirements of *Virginia Code* § 32.1-162.18 and the requirements of 6 VAC 35-170-80. Any form used must be understandable to potential participants.
9. Special Provisions Regarding Informed Consent
 - a. In accordance with *Virginia Code* § 32.1-162.18.C., the Committee may waive the requirement to obtain informed consent or may approve a consent process that omits or alters some or all of the basic elements of informed consent if the Committee finds and documents that the proposed research meets all of the requirements of 6 VAC 35-170-160.B.
 - b. In accordance with *Virginia Code* § 32.1-162.18.D., the Committee may waive the required informed consent for some or all subjects when the conditions detailed in 6 VAC 35-170-160.D are met.
10. After reviewing the human research proposal, the Committee may:
 - a. Recommend that the Department Director approve the research;
 - b. Reject the research proposal as inconsistent with any of the provisions of *Virginia Code* §§ 32.1-162.16, et seq., inconsistent with Department policies and procedures, or incompatible with available resources; or
 - c. Defer a recommendation pending receipt of additional information or modification of the proposal by the Principal Researcher.
11. The Coordinator of External Research will submit the Research Proposal; the Research Agreement, signed by the researcher; and the Committee's recommendation to the Department Director.
12. The Department Director will approve or deny the proposal within 10 business days of receiving the recommendation and will communicate the approval or denial to the Legislative and Research Manager and the Coordinator of External Research. The Department Director may reject the recommendation of approval upon finding the research proposal is inconsistent with any of the provisions of *Virginia Code* §§ 32.1-162.16, et seq., or Department policies and procedures, or is incompatible with available resources; and may set conditions on the research, which shall be put in writing.

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13. Within five business days of receiving the decision of the Department Director, the Coordinator of External Research shall:
 - a. Notify the researcher that the proposal was not approved; or
 - b. If the research proposal was approved, send the signed Research Agreement to the Principal Researcher. The Research Agreement will outline the respective responsibilities of the parties and will specify:
 - 1) When progress reports shall be required, if applicable;
 - 2) The Department shall have unrestricted permission to use the research findings in accordance with professional standards of research;
 - 3) A final report shall be submitted electronically to the Coordinator of External Research;
 - 4) All external articles, reports, and presentations made from the data shall be submitted electronically to the Coordinator of External Research and shall include the statement, "The findings of this study are the responsibility of the researchers, and cooperation by the Virginia Department of Juvenile Justice in facilitating this research should not be construed as an endorsement of the conclusions drawn by the researchers;" and
 - 5) The Research Agreement is not effective until signed by both the Principal Researcher and the Department Director.

G. Review of Modifications to Approved Human Research

1. The following process shall be followed to request and approve a modification to an approved project:
 - a. The Principal Researcher shall submit a red line version (e.g., Track Changes) and clean version of the modified Research Proposal form via email to the Coordinator of External Research.
 - b. Within 10 business days of receiving the research proposal, the Coordinator of External Research will consult with the Legislative and Research Manager to determine if the requested modifications substantively change the criteria considered in the original review. If so, full review is required and shall follow the process described above for new proposals. If not, the Legislative and Research Manager may approve the modifications under expedited review. The Coordinator of External Research shall notify the Principal Researcher of the decision.

H. Review of Human Research in Progress

1. In accordance with *Code of Virginia* § 32.1-162.19 and the Virginia Administrative Code 6VAC35-170-180, the Committee shall require periodic reports from each human research project and conduct a review at least annually to ensure that the project is being carried out in conformity with the proposal as approved.
2. The Principal Researcher shall report to the Coordinator of External Research all protocol violations, including (but not limited to) the reporting of adverse events, sponsor-imposed or IRB-imposed protocol suspensions, protocol deviations/violations, confidentiality breaches, and participant complaints. Reports must be submitted within five business days of the Principal Researcher's knowledge of the incident. The report shall include relevant dates, times, locations, personnel involved, event details, and actions taken and planned.

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- a. Within five business days, the Coordinator of External Research shall disseminate the report via email to the Committee for review.
 - b. Within 10 business days, the Committee shall recommend further action to the Department Director.
 - c. Within 10 business days, the Department Director shall make a final determination of further action.
 - d. Within five business days, the Coordinator of External Research will notify the Principal Researcher of the decision.
3. The following actions may be taken at any time if a research project deviates significantly from the proposal as approved or from any conditions imposed by the Department Director or increases the level of harm to participants or others:
- a. Require the investigator to submit a report to their IRB, copying the Coordinator of External Research on all correspondence;
 - b. Temporarily halt research activities until a corrective action plan can be approved and implemented; and
 - c. Revoke approval of the research in whole or part.

I. Annual Reporting

1. The Committee shall submit annually to the Governor, the General Assembly, the Board of Juvenile Justice, and the Department Director a report on the human research projects reviewed and approved by the Committee, including any research that has deviated from the research design as approved.

V. RESPONSIBILITY

All organizational unit heads shall have primary responsibility for referring requestors to this procedure. The Coordinator of External Research shall have primary responsibility for implementation and ensuring compliance with this procedure.

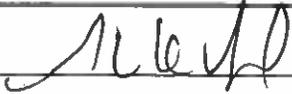
VI. INTERPRETATION

The Legislative and Research Manager shall be responsible for interpreting and granting any exceptions to this procedure.

VII. CONFIDENTIALITY

All procedures are DJJ property and shall only be used for legitimate business purposes. Any redistribution of the documents or information contained in the procedures or bulletins shall be in accordance with applicable state and federal statutes and regulations and all other DJJ procedures. Any unauthorized use or distribution may result in disciplinary and/or criminal action, as appropriate and applicable.

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Approved by: 	Date: 6/2/16
Effective Date: July 7, 2016	Office of Primary Responsibility: Legislative and Research Division
Supersedes: 07-006.3 Review and Approval of Research Proposals (August 2, 2005)	Forms: Confidentiality Agreement; HRRC Proposal Form; Research Agreement