Department of Juvenile Justice
Guidance Document Interpreting 6VAC35-170
Review and Approval of Data Requests and Research Proposals

In accordance with § 2.2-4002.1 of the Code of Virginia, this proposed guidance document conforms to the definition of a guidance document in § 2.2-4101.

I. PURPOSE

This guidance document provides the process for the review and approval of four types of external data requests and research proposals. These include (1) external aggregate data requests, (2) Virginia Longitudinal Data System requests, (3) external case-specific data requests, and (4) human research proposals.

This guidance document implements and must be applied in conjunction with the Regulation Governing Juvenile Data Requests and Research Involving Human Subjects (6VAC35-170) 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 AND GENERAL INFORMATION

This guidance document describes how data requests and research proposals will be submitted, reviewed, approved, and coordinated. This guidance document does not apply to quality or process improvement projects.

The department may charge requestors reasonable fees to offset costs incurred in supporting specific projects.

III. DEFINITION

The following words and terms, when used in this guidance document, shall have the following meanings unless the context clearly indicates otherwise:

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

***Case-specific Data* -** Nonaggregated data that provides information about individuals within a group.

***Coordinator of External Research* -** The department employee in the research unit designated by the director to receive research proposals and data requests from external entities and to ensure that the proposals are reviewed in accordance with this guidance document and with 6VAC35-170.

De-identified Data - Data with common identifiers, such as names, phone numbers, social security numbers, and addresses 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 or the director's designee.

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

Human Research - A systematic investigation, including research development, testing, and evaluation, utilizing human subjects that is designed to develop or contribute to generalized knowledge. Human research shall not be deemed to include research exempt from federal research regulation pursuant to 45 CFR 46.101(b).

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

Human Subject - An individual who is under the department's care, custody, or supervision; under the care, custody, or supervision of a facility or program regulated by the department or the Board of Juvenile Justice; or a member of the family of such an individual and who is, or who is proposed to be, a subject of human research. For purposes of this definition, human subject also means an individual who is employed in or provides contractual services to a juvenile correctional center or other facility or program regulated by the department or the Board of Juvenile Justice and who is or who is proposed to be a subject of human research.

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 choice. The basic elements necessary for informed consent regarding human research include:

1. A reasonable and comprehensible explanation to the person of the proposed procedures and protocols to be followed; their purposes, including descriptions of attendant discomforts; and the risks and benefits reasonably to be expected;
2. A disclosure of alternative procedures or therapies that might be helpful to the person;
3. An instruction that the person may withdraw consent and stop participating in the human research at any time without prejudice;
4. An explanation of costs or compensation that may accrue to the person and whether third party reimbursement is available for the proposed procedures or protocols; and
5. An offer to answer, and answers to, questions by the person about the procedures and protocols.

Internal Committee - The committee established by the department pursuant to 6VAC35-170-65 to oversee de-identified case specific data.

Legally Authorized Representative - The parent having custody of a prospective subject; the legal guardian of a prospective subject; or any person or judicial or other body authorized by law to consent on behalf of a prospective subject to such subject's participation in the particular human research, including an attorney in fact appointed under a durable power of attorney, provided the power grants the authority to make such a decision. For purposes of this guidance document, "legally authorized representative" shall not include an official or employee of the institution or agency conducting or authorizing the research.

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 Head - The person in charge of a juvenile correctional center, court service unit, or other organizational unit of the department or a Board of Juvenile Justice-regulated facility, program, or service.

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

Research - The systematic development of knowledge essential to effective planning and rational decision-making. It involves the assessment of current knowledge on conceptual problems selected, the statement of those problems in researchable format, the design of methodologies appropriate to the problems, and the application of statistical techniques to organize and analyze data.

Researcher - An individual conducting research.

Research Project - The systematic collection of information, analysis of the data, and the preparation of a report of findings.

Sensitive Data - Data, the compromise of which, with respect to confidentiality, integrity, or availability, could have a material adverse effect on agency programs or the privacy to which individuals are entitled.

Virginia Longitudinal Data System (VLDS) - A data system that provides de-identified case-specific data from participating agencies to qualified researchers through a process that involves submission of requests and approval or denial by each sponsoring agency from which data are sought in an effort to create usable information for policy and generate cross-agency research.

Written - The required information is communicated in writing either in hard copy or electronic form.

IV. PROCEDURES

A. External Aggregate Data Requests

1. External aggregate data requests shall be submitted to the Research Manager or designee via a detailed email outlining the specific information requested.

2. The Research Manager or designee shall determine the following prior to approving aggregate data requests:

    a. That the request meets the conditions for department approval of research identified in 6VAC35-170-30 and 6VAC35-170-50;
    b. Whether the data requested is accessible;
    c. An estimate of the time required to process the data request; and
    d. Based on staff workload, whether staff resources are available to process the data request.

3. The Research Manager or designee, as the director's designee, may approve and coordinate the provision of data.

4. The Research Manager or designee, as the director's designee, shall notify the requestor of the approval or denial of the data request with the rationale for the decision within 20 business days of receiving the request.

5. If the data request is approved, the Research Manager or designee shall provide the requestor with an estimated timeline for receipt of the data.

B. VLDS Requests

1. If requesting the department as the sponsor agency of a VLDS data request, the forms and review process for external de-identified case-specific data requests, described in subsection C of this guidance document, shall be completed prior to submission using the VLDS portal. External case-specific data requests submitted through the VLDS with a different sponsor agency are not required to complete or submit the Research Proposal Form prior to submission using the VLDS portal.

2. All external case-specific data requests submitted through the VLDS shall be submitted to the department using the VLDS portal.

3. The researcher shall comply with all VLDS procedures in order to access data through the VLDS.

4. The chair of the HRRC shall have primary responsibility for reviewing and approving requests submitted through the VLDS portal. The chair of the HRRC may not approve an external case-specific data request unless the request meets the following requirements:

    a. The request satisfies the conditions for department approval of research identified in 6VAC35-170-30 and 6VAC35-170-50;
    b. The request is not a human research proposal and does not require the HRRC's review;

c. The request is in the required format and includes all required information;
d. The request complies with basic research standards and applicable laws; and
e. The data requested are accessible and available in the VLDS.

5. Upon reviewing the data request, the chair of the HRRC may restrict the scope of the data, provided the data requested are unrelated to the purpose of the research study.

6. The following process shall be followed for requests to modify an approved VLDS project:

   a. If sponsored by the department, the same process as described in this guidance document for modifications to external case-specific data requests shall be followed. Approval must occur prior to submitting an amendment in the VLDS portal.
   b. If sponsored by a different agency, the researcher is not required to receive approval prior to submitting an amendment in the VLDS portal.

C. General Requirements for External De-Identified Case-Specific Data Requests and Human Research Proposals

1. External data requestors, external researchers, and department personnel proposing to conduct human research all will follow the same steps in submitting proposals for the department's consideration. If a project involves both an external de-identified case-specific data request and a human research proposal, the process for approving a human research proposal shall be followed to approve the project as a whole.

2. The department's website shall include information on requesting data and conducting research with 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 may not redisclose or otherwise reveal the juvenile record information of an individual, beyond the purpose for which the original disclosure was made. The prohibition on redisclosure shall not prevent the external data requestors and researchers from 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 de-identified case-specific data requests and research proposals shall be submitted to the Coordinator of External Research using the Confidentiality Agreement Form, the Research Proposal Form, the Research Agreement Form, and any required attachments. The principal researcher shall provide the Coordinator of External Research an electronic copy of the forms via email.

5. The Research Agreement Form must be signed by the principal researcher(s) and the student researcher (if applicable) at the time of submission.

6. The Confidentiality Agreement Form must be signed by every individual who may access the data.

7. The Research Proposal Form shall contain the following elements:

    a. Name, address, telephone number, email address, title, and affiliation of the principal researcher(s) (for student projects, the principal researcher must be the academic advisor rather than the student);
    b. Name, telephone number, and email address of the person who will coordinate the project, if different from the principal researcher;
    c. Resume or Curriculum Vitae for principal researcher(s) and students (if applicable);
    d. Funding source, if any;
    e. Date of the proposal's submission to the department;
    f. Title or descriptive name of the proposed project;
    g. Statement of the specific purpose(s) of the proposed research project with anticipated results, including benefit to the department;
    h. A concise description of the research design and techniques for data collection and analysis and of the likely effects of the research methodology on existing programs and institutional operations;
    i. Timeframes indicating proposed beginning and ending dates for data collection, analysis, preliminary report, and final report;
    j. A list of 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;
    k. Identification of the organizational unit where the research will be conducted and letter of support acknowledging the organizational unit's agreement to participate in research-related activities, if applicable.
        i. Pursuant to the regulation, if the external research is proposed to take place in a particular organizational unit, the principal researcher shall present a preliminary research proposal to the organizational unit head and get the organizational unit head's written endorsement.
        ii. The organizational unit head supporting the project is responsible for requesting a written endorsement from the deputy director of the appropriate division prior to the submission of the proposal packet to the Coordinator of External Research.);
    l. Endorsement from the Institutional Review Board (IRB) of the institution or organization with which the researcher is affiliated; and
    m. A signed and dated statement that the principal researcher and the research staff have read and understand 6VAC35-170, this guidance document, and the Research Agreement Form.

8. The Research Agreement Form shall outline the respective responsibilities of the parties and shall specify the following:

    a. The frequency with which progress reports shall be required;
    b. The department's unrestricted authority to use the research findings in accordance with professional standards of research;
    c. The principal researcher's obligation to submit a formal final report electronically, with an executive summary to the Coordinator of External Research;
    d. Whether the department requires pre-review and approval by the department prior to external publications;
    e. That, unless waived by the director, all external articles, reports, presentations, and publications made from the data collected shall be submitted electronically to the Coordinator

of External Research within 30 days of the publication or presentation date, and all materials shall include the statement, "The findings of this study are the responsibility of the researchers, and cooperation by DJJ in facilitating this research should not be construed as an endorsement of the conclusions drawn by the researchers";

f. That, if the statement above is waived, all external articles, reports, presentations, and publications shall be reviewed and approved by the department prior to being released. Materials shall be submitted to the Coordinator of External Research at least 30 days prior to the anticipated submission date; and
g. That the Research Agreement Form is not effective until signed by both the principal researcher and the director.

9. Industry standard levels of encryption shall be required to protect all juvenile record information provided to researchers.

10. The principal researcher must comply with the research plan stated in the Research Proposal Form, including the plan for disseminating findings. Requests for changes to the research plan must be submitted to the Coordinator of External Research and approved by the department before being implemented.

11. The Coordinator of External Research shall distribute the findings of all external research projects as appropriate.

D. External Case-Specific Data Requests

1. The department considers the following identifiers to be sensitive data and shall be removed from the data provided to researchers:

   a. Names;
   b. Dates of birth;
   c. Postal street addresses;
   d. Telephone numbers;
   e. Email addresses;
   f. Social security numbers;
   g. Medical record numbers;
   h. Biometric identifiers, including finger and voice prints; and
   i. Full face photographic images and any comparable images.

2. The department may consider the following identifiers as sensitive data based on the details of the project and other information included in the data set, and may remove such identifiers from the data provided to researchers:

   a. Dates (date of admission, date of release, etc.);
   b. Location information more detailed than town or city, state, and zip code; and
   c. Account numbers (Juvenile Number, Direct Care Number, etc.).

3. The director, on a case-by-case basis, may approve the dissemination of the identifiable data for research benefiting the department, provided the researcher agrees that any such information will

be released or published only in aggregate form or kept confidential in accordance with the following requirements:

a. Research findings shall not identify individual subjects.
b. All records and all information given by research subjects or employees of the department shall be kept confidential in accordance with § 16.1-300 of the Code of Virginia and applicable rules and regulations regarding confidentiality of juvenile records.
c. Persons who breach confidentiality shall be subject to sanctions in accordance with applicable laws, regulations, policies, and procedures.
d. Confidentiality does not preclude reporting results utilizing de-identified data or giving raw data to the department for possible further analysis.

4. If sensitive data are provided, the researchers must follow the human research review process and must comply with appropriate security (e.g., Commonwealth's Information Security Standard SEC-501) and non-disclosure requirements. The department may require completion of additional forms or agreements for sensitive data requests.

5. Within 10 business days of receiving the data request, the Coordinator of External Research shall determine the following:

a. The request meets the conditions for department approval of research identified in 6VAC35-170-30;
b. The proposal is not a human research proposal and is not required to be reviewed by the HRRC; however, requests that include sensitive data shall be reviewed by the HRRC;
c. The principal researcher has the appropriate academic or professional standing or job-related experience in the area to be studied;
d. The proposal is in the required format and includes all required information;
e. The proposal complies with basic research standards and applicable laws;
f. The data requested is accessible;
g. Department staff and resources are available to process the data request; and
h. An estimate of the time required to compile the data request.

6. The Research Manager shall assess staff workload and resources and determine if staff and resources are available to process the data request, as required.

7. An internal committee, chaired by the Research Manager who designates committee members, shall act on a research proposal within 20 business days. The internal committee may meet in person, by conference call, or via email. The internal committee shall determine that the proposal meets the following conditions set forth in 6VAC35-170-50:

a. The department has sufficient financial and staff resources to support the request, and that on balance the benefits of the request justify the department's involvement;
b. The request will not interfere significantly with the department's programs or operations, particularly those of the operating units that would participate in the proposed research; and
c. The request is compatible with the purposes and goals of the juvenile justice system and with the department's organization, operations, and resources.

8. In addition, the internal committee shall:

    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 protected adequately.
    d. Make a written recommendation to the director to approve or disapprove the request.

9. The Coordinator of External Research shall submit the Research Proposal Form, the Research Agreement Form signed by the researcher, and the internal committee's recommendation to the director for review.

10. The director shall approve or deny the proposal within 10 business days of receiving the recommendation and shall communicate the approval or denial to the Research Manager and the Coordinator of External Research.

11. Within five business days of receiving the director's decision, the Coordinator of External Research shall:

    a. Notify the researcher that the proposal was not approved and provide a rationale for the denial; or
    b. Provide the principal researcher a final copy of the Research Agreement Form containing the director's signature if the research proposal is approved.

12. The following process shall be followed for requests to modify an approved project:
    a. The principal researcher shall submit a redline 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 shall consult with the Research Manager to determine if the requested modifications substantively change the criteria considered in the original review or alter the scope of the study.
    c. If the revision is substantive, a full review is required and shall follow the process described above for new proposals. If the revision is not substantive, the Research Manager may conduct an expedited review of the amendment. Additional review or approval by the internal committee or director shall not be required.
    d. The Coordinator of External Research shall notify the principal researcher of the decision.

E. Human Research General Provisions

1. The following categories of human research are not subject to 6VAC35-170 nor this guidance document. Except as otherwise provided by law or regulation, these activities shall be subject to the nonhuman research review and approval process established by the department.
    a. Activities of the Virginia Department of Health conducted pursuant to § 32.1-39 of the Code of Virginia.
    b. Research or student learning outcomes assessments conducted in educational settings involving regular or special education instructional strategies; the effectiveness of or the

comparison among instructional techniques, curricula, or classroom management methods; or the use of educational tests, whether cognitive, diagnostic, aptitude, or achievement, if the data from such tests are recorded in a manner so that subjects cannot be identified, directly or through identifiers linked to the subject.

c. Research involving solely the observation of public behavior, including observation by participants, or research involving survey or interview procedures unless subjects can be identified from the data either directly or through identifiers linked to the subjects, and either:
    i. The information about the subject, if it became known outside the research, reasonably could place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability; or
    ii. The research deals with sensitive aspects of the subject's own behavior, such as sexual behavior, drug or alcohol use, or illegal conduct.
d. The collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the subjects cannot be identified from the information either directly or through identifiers linked to the subjects.
e. Medical treatment of an experimental nature intended to save or prolong the life of the subject in danger of death, to prevent the subject from becoming disfigured or physically or mentally incapacitated, or to improve the quality of the subject's life.
f. Pursuant to 45 CFR 46.101, the exemptions outlined in this section shall not apply to research conducted upon individuals involuntarily confined in a penal institution, including individuals committed to a juvenile correctional center or juvenile secure detention center.
g. Pursuant to 45 CFR 46.101, the exemptions outlined in subdivision A(3) of this federal provision shall not apply to research conducted on children who have not attained age 18 years.

2. Human research that is not exempted by § 32.1-162.17 of the Code of Virginia requires endorsement from the IRB of the institution or organization with which the researcher is affiliated.

3. Human research involving known and substantive physical, mental, or emotional risk to subjects, including the withholding of any prescribed program of treatment, and all experimental medical, pharmaceutical or cosmetic research, are specifically prohibited.

4. No human research shall be conducted without the review of the HRRC and approval by the department.

5. At the request of the researcher, the HRRC may conduct an expedited review when the proposed research involves no more than minimal risk to the human subjects and the proposal has been reviewed and approved by another agency’s HRRC.

6. Offering incentives to participate in research is discouraged but not prohibited. Incentives shall be appropriate to the juveniles' custodial status and proportionate to the situation.

7. The principal researcher shall be responsible for the conduct of the research staff, the protection of the rights of subjects involved in the project, and the provision of information required by the coordinator of external research, organizational unit heads, and the HRRC.

F. Human Research Review Committee

1. The department shall establish an HRRC composed of persons representing diverse backgrounds relative to both work and life experience as well as race, ethnicity, gender, and other characteristics. The HRRC shall ensure the competent, complete, and professional review of human research activities conducted or proposed to be conducted or authorized by the department.

2. The Research Manager shall keep a current listing of members of the HRRC.

3. The HRRC shall consist of at least seven persons, including:

    a. The Research Manager, who will serve as chair;
    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, clergyperson); and
    e. At least one person with the background and experience to advocate for the welfare of human research subjects.

4. Committee members shall be chosen by the chair of the HRRC with input provided by current HRRC members and other department staff. Committee members shall serve two-year terms with the option to renew.

5. HRRC Operation:

    a. The HRRC shall meet as often as necessary to give timely consideration to human research proposals. Whenever practicable, proposals shall be emailed to the HRRC members, who shall act on a research proposal within thirty business days of receipt.
    b. An HRRC member who is directly involved in a research project or has administrative authority over a research project apart from the member's role on the HRRC may not vote on such research.
    c. A simple majority of HRRC members constitutes a quorum. The HRRC may meet in person, by conference call, or via email.
    d. The HRRC 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 HRRC makes its decision.
    e. The HRRC may require additional information from the researcher before making a recommendation to the director.

G. Review of Human Research Proposals

1. Within 10 business days of receiving the research proposal, the Coordinator of External Research shall 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 HRRC; and
g. The data requested is accessible, if applicable.

2. If the Coordinator of External Research, after consulting with the 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.
3. If the proposal is not denied, the Coordinator of External Research will notify the principal researcher of any necessary changes, additional information, or clarifications.

4. Within 10 business days of receiving a research proposal that complies with all criteria considered by the Coordinator of External Researcher, the proposal shall be distributed via email to the HRRC.

5. The HRRC shall review the proposal within 30 business days and make a recommendation to the director.

6. In reviewing a human research proposal, the HRRC must determine that the proposal meets the following conditions set forth in 6VAC35-170-50:

   a. The department has sufficient financial and staff resources to support the request, and that on balance the benefits of the request justify the department's involvement;
   b. The request will not interfere significantly with the department's programs or operations, particularly those of the operating units that would participate in the proposed research; and
   c. The request is compatible with the purposes and goals of the juvenile justice system and with the department's organization, operations, and resources.

7. In reviewing a human research proposal, the HRRC also shall consider whether:

   a. The research's potential risks and benefits are adequately described;
   b. The benefits to the human subjects outweigh the risks;
   c. The methodology is adequate for the proposed research;
   d. The nontherapeutic research presents more than a minimal risk to the human subjects;
   e. The rights and welfare of the human subjects are adequately protected;
   f. The researchers are appropriately competent and qualified;
   g. The criteria for selecting subjects are valid and equitable;
   h. The research complies with the requirements set out in 6VAC35-170 and this guidance document; and

i. Informed consent will be obtained by methods that are adequate, appropriate, and in accordance with the requirements of § 32.1-162.18 of the Code of Virginia, 6VAC35-170-80, and 6VAC35-170-160. Any form used must be understandable to potential participants.

8. Informed Consent

a. Virginia law sets out the following requirements regarding informed consent for research involving human subjects:
   i. Except as provided elsewhere in Chapter 5.1 of Title 32.1 (§ 32.1-162.16 et seq), no researcher may involve a human subject in human research without first obtaining the informed consent of the human subject or his legally authorized representative. A researcher shall seek such consent only under circumstances that provide the human subject or the legally authorized representative sufficient opportunity to consider whether to participate and that minimize the possibility of coercion or undue influence.
   ii. If a human subject is competent, informed consent shall be given in writing by the subject and witnessed.
   iii. If a human subject is not competent, informed consent shall be given in writing by the subject's legally authorized representative and witnessed.
   iv. If a human subject is a minor who is otherwise capable of giving informed consent, informed consent shall be given in writing by both the minor and his legally authorized representative.
   v. If two or more persons who qualify as legally authorized representatives with decision-making authority inform the researcher that they disagree as to the participation of the human subject, the subject shall not be enrolled in the human research that is the subject of the consent.
   vi. Notwithstanding consent by a legally authorized representative, no person who is otherwise capable of giving informed consent shall be forced to participate in human research.
   vii. A legally authorized representative may not consent to nontherapeutic research unless the HRRC determines that the research will present no more than a minimal risk to the human subject.

b. The informed consent form shall not include any language through which the human subject waives or appears to waive any legal right, including the release of an individual, institution, or agency or any agent thereof from liability for negligence.

c. The HRRC:

   i. Shall review and approve the consent process and all required consent forms for each proposed human research project before recommending approval to the director.

   ii. May approve a consent procedure that omits or alters some or all of the basic elements of informed consent or waives the requirement to get informed consent if the HRRC finds and documents that:

      a. The research involves no more than a minimal risk to the subjects;

b. The omission, alteration, or waiver will not adversely affect the rights and welfare of the subjects;
c. The research could not be performed practicably without the omission, alteration, or waiver; and
d. After participation, the subjects will be given additional pertinent information when appropriate.

iii. May waive the requirement that the researcher get written informed consent for some or all subjects if the principal risk would be potential harm resulting from a breach of confidentiality and the only record linking the subject and the research would be the consent document. The HRRC may require the researcher to give the subjects and legally authorized representatives a written statement explaining the research. Further, the researcher shall ask each subject whether he wants documentation linking him to the research, and the subject's wishes shall govern.

9. After reviewing the human research proposal, the HRRC may:

a. Recommend that the director approve the research;
b. Recommend that the director reject the research proposal as inconsistent with the provisions of §§ 32.1-162.16, et seq. of the Code of Virginia, inconsistent with the department's 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.

10. The Coordinator of External Research shall submit the Research Proposal Form, the Research Agreement Form signed by the researcher, and the HRRC's recommendation to the director.

11. The director shall approve or deny the proposal within 10 business days of receiving the recommendation and shall communicate the approval or denial to the Research Manager and the Coordinator of External Research. The director may reject the approval recommendation upon finding the research proposal is inconsistent with any of the provisions of §§ 32.1-162.16, et seq. of the Code of Virginia or the department's procedures, or is incompatible with available resources. The director also may set conditions on the research, which shall be put in writing.

12. Within five business days of receiving the director's decision, the Coordinator of External Research shall:

a. Notify the principal researcher of the director's final decision;
b. If the research proposal was approved, send the signed Research Agreement Form to the principal researcher.

H. 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 redline 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 shall consult the Research Manager to determine if the requested modifications substantively change the criteria considered in the original review or alter the scope of the study.

c. If the revision is substantive, a full review is required and shall follow the process described above for new proposals. If the revision is not substantive, the chair of the HRRC may conduct an expedited review of the amendment. Additional review or approval by the HRRC or director shall not be required.

d. The Coordinator of External Researcher shall notify the principal researcher of the final decision.

I. Review of Human Research in Progress

1. In accordance with § 32.1-162.19 of the Code of Virginia and 6VAC35-170-180, the HRRC shall review all human research activities at least annually to ensure that the project is conducted in conformance with the proposal as approved by the director.

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.

    a. Within five business days of receiving the report, the Coordinator of External Research shall disseminate the report via email to the HRRC for review.
    b. Within ten business days of receiving the report, the HRRC shall recommend further action to the director.
    c. Within ten business days of the HRRC's recommendation, the director shall make a final determination of further action.
    d. Within five business days of the director's determination, the Coordinator of External Research shall 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 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.

J. Researcher Non-Compliance

1. The researcher shall report noncompliance with the approved research proposal to the HRRC and the IRB.
2. If the HRRC determines that the research activities fail to comply with the approved proposal or violate the Code of Virginia or the Virginia Administrative Code, the department may restrict or terminate further research, prohibit the researcher from presenting or publishing the research results, and/or bar the researcher from conducting future studies.

K. Annual Reporting

The HRRC shall submit to the Governor, the General Assembly, the Board of Juvenile Justice, and the director at least annually a report on human research projects approved by the HRRC and the status of such research, including any significant deviation from the proposals as approved. The report shall include a summary of approved human research projects and the results of such projects and be posted on the department's website unless otherwise exempt from disclosure under the Virginia Freedom of Information Act (§ 2.2-3700 et seq. of the Code of Virginia).

V. RESPONSIBILITY

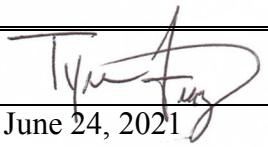
All organizational unit heads shall have primary responsibility for referring requestors to this guidance document. The Coordinator of External Research shall have primary responsibility for implementing and ensuring compliance with this guidance document.

VI. INTERPRETATION

The Deputy Director of Administration and Finance or designee shall be responsible for interpreting and granting any exceptions to this guidance document.

VII. REVIEW DATE

This guidance document shall remain in effect until rescinded or otherwise modified by the Board of Juvenile Justice.

Approved by: 	**Date:** June 24, 2021
Effective Date: June 24, 2021	**Office of Primary Responsibility:** Research Manager; Data Manager; Coordinator of External Research