DRAFT Revision date: 7 23 2002

MINIMUM STANDARDS FOR RESEARCH INVOLVING HUMAN SUBJECTS OR RECORDS OF THE DEPARTMENT OF JUVENILE JUSTICE

Board of Juvenile Justice

6 VAC 35-170-10. Definitions.

Unless the context clearly indicates otherwise, the following words and terms, when used in this regulation, shall have the following meanings, consistent with the definitions offered in Code of Virginia Section 32.1-162.16:

"Coordinator of external research" is the Department employee designated by the Director to receive research proposals from external entities and ensure that the proposals are reviewed in accordance with this regulation and related Department procedures.

"Department" means the Department of Juvenile Justice.

"Director" means the Director of the Department of Juvenile Justice, or his designee.

"Human Subject" means any individual who is under the Department's care or custody, or a member of the family of such an individual, who is or who is proposed to be a subject of human research.

"Human research" means any systematic investigation using human subjects, which may expose those subjects to physical or psychological injury, and which departs from the application of established and accepted therapeutic methods appropriate to meet the subject's needs.

"Informed consent" means 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 any attendant discomforts, and risks and benefits reasonably to be expected;

2. A disclosure of any alternative procedures or therapies that might be advantageous for the person;

3. An instruction that the person may withdraw his consent and discontinue participation in the human research at any time without prejudice to him;

4. An explanation of any costs or compensation which may accrue to the person and, if

applicable, the availability of third party reimbursement for the proposed procedures or protocols; and

5. An offer to answer, and answers to, any inquiries by the person concerning the procedures and protocols.

"Legally authorized representative" means the parent or parents 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 and the attorney in fact is not employed by the person, institution, or agency conducting the human research. No official or employee of the institution or agency conducting or authorizing the research shall act as a legally authorized representative.

"Minimal risk" means that 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.

"Non-therapeutic research" means 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" means the person in charge of a juvenile correctional center, halfway house, court service unit, regional office or other organizational unit of the Department.

"Principal researcher" means the individual who is responsible for the research design, the conduct of research, supervising any research staff, and the research findings.

"Research" means the systematic development of knowledge essential to effective planning and rational decision-making. It involves the assessment of current knowledge on conceptual problems selected, statement of those problems in researchable format, design of methodologies appropriate to the problems, and the application of statistical techniques to organize and analyze data. Research findings should provide valuable information to management for policy options.

"Researcher" means an individual conducting research who has professional standing in the pertinent field or is supervised directly by such an individual.

"Research project" means the systematic collection of information, analysis of the data, and the preparation of a report of findings.

6 VAC 35-170-20. General requirements of external researchers.

A. The principal researcher shall have academic or professional standing in the pertinent field or job-related experience in the areas of study or be directly supervised by such a person.

B. The principal researcher is responsible for (i) the conduct of the research staff, (ii) the protection of the rights of subjects involved in the project, and (iii) providing the information required by the coordinator of external research, organizational unit heads, and the Human Research Review Committee.

6 VAC 35-170-30. Professional ethics.

The research shall conform to the standards of ethics of professional societies such as the American Correctional Association, the American Psychological Association, the American Sociological Association, the National Association of Social Workers, or their equivalent.

6 VAC 35-170-40. Confidentiality requirements of all research.

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 Section 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 in a consolidated form that protects the identity of individuals, or giving raw data to the Department for possible further analysis.

6 VAC 35-170-50. Conditions for Department approval of external research.

A. The Department will approve research projects only when it determines, in its sole discretion, that:

1. The Department has sufficient financial or personnel resources to support the research project, and that on balance the benefits of the research justify the Department's involvement;

2. The proposed research will not interfere significantly with the programs or operations of

the Department, particularly those of the operating units that would participate in the proposed research; and

4. The proposed research is compatible with the purposes and goals of the juvenile justice system and with the Department's organization, operations, and resources.

6 VAC 35-170-60. Formal agreement required.

No external research shall begin until all reviews required by this regulation and Department procedure have been completed and the principal researcher is given a copy of the research agreement signed by the Director.

6 VAC 35-170-70. Requirements specific to human research.

A. All human research shall comply with all applicable laws, particularly Chapter 5.1 of Title 21.1 and Chapter 5.1 (§ 32.1-162.16 et seq.) of Title 32.1 of the Code of Virginia regarding human research.

B. 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.

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

D. No human research shall be conducted without the approval of the Human Research Review Committee.

6 VAC 35-170-80. Informed consent required for human research. (See COV. § 32.1-162.18)

A. If a human subject is competent, informed consent shall be subscribed to in writing by the person and witnessed.

B. If a human subject is not competent, informed consent shall be subscribed to in writing by the person's legally authorized representative and witnessed.

C. If a human subject is a minor who is otherwise capable of giving informed consent, informed consent shall be subscribed to in writing by both the minor and his legally authorized representative.

D. Notwithstanding consent by a legally authorized representative, no person who is otherwise capable of giving informed consent shall be forced to participate in any human research.

E. A legally authorized representative may not consent to non-therapeutic research unless the Human Research Review Committee determines that such non-therapeutic research will present no more than a minimal risk to the human subject.

F. No informed consent form shall include any language through which the human subject waives or appears to waive any legal rights, including any release of any individual, institution, or agency or any agents thereof from liability for negligence. (See COV. § 32.1-162.18)

6 VAC 35-35-90. Exemptions from the requirements governing human research.

In accordance with Code of Virginia Section 32.1-162.17, the following categories of human research are not subject to this regulation's provisions governing human research. Except when provided for by law or regulation, these activities may be subject to the non-human research review and approval process established by the Department.

1. Activities of the Virginia Department of Health conducted pursuant to §32.1-39 of the Code of Virginia;

2. 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 recorder in a manner so that subjects cannot be identified, directly or through identifiers linked to the subject.

3. Research involving solely the observation of public behavior, including observation by participants, or research involving survey of interview procedures unless data are recorded in such a manner that the subjects can be identified, directly of through identifiers linked to the subjects, and either:

a. The information about the subject, if it become known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects's financial standing or employability; or

b. The research deals with sensitive aspects of the subject's own behavior, such as

sexual behavior, drug or alcohol use, or illegal conduct.

4. The collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in a manner so that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. 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, physically or mentally incapacitated, or to improve the quality of the subject's life.

6 VAC 35-170-100. Proposal for External Research.

A. If the principal researcher knows where the research will be conducted if approved, the principal researcher shall present a preliminary research proposal to the organizational unit head where the proposed research is to be conducted, and obtain the endorsement of the organizational unit head for the proposal, in accordance with procedures established by the Department.

B. If the principal researcher does not know where the research will be conducted if approved, or if the principal researcher has obtained the endorsement of the organizational unit head where the research is proposed to be conducted, the principal researcher shall submit to the coordinator of external research a complete research proposal describing the research project, and containing:

1. Name, address, telephone numbers, title and affiliation of the principal researcher;
2. Name of the person who will immediately supervise the project, if different from the principal researcher identified in #1, above.
3. Funding source, if any;
4. Date of the proposal's submission to the Department;
5. Title or descriptive name of the proposed research project;
6. Statement of the specific purpose(s) of the proposed research project with anticipated results, including benefit to the Department;
7. 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;
8. Time frames indicating proposed beginning and ending dates for (i) data collection, (ii) analysis, (iv) preliminary report, and (v) final report;
9. A listing of any resources the researcher will require from the Department or its units, such as personnel, supplies, materials, equipment, work spaces, or access to clients and files.

10. Endorsement from the Department operating unit that is to participate in the research (e.g. Juvenile Correctional Center, Court Services Unit, etc.);
11. For student research, endorsement from the researcher's academic advisor or other appropriate persons;
12. For research involving records of juveniles at state and local court service units, endorsement from the appropriate juvenile and domestic relations judge(s);
13. For human research, endorsement from the institutional review board of the institution or organization with which the researcher is affiliated; and
14. For all research projects, a signed and dated "Research Agreement" (see example attached) indicating that the principal researcher and research staff have read, understand, and agree to abide by these regulations.

6 VAC 35-170-110. Initial review by coordinator of external research.

The coordinator of external research shall:

1. receive all research proposals from external researchers;
2. review the proposals to ensure that they are in the required format and include all required information;
3. confirm that the proposed research is consistent with basic research standards and applicable laws; and
4. refer the proposals to appropriate Department personnel for review, which shall include, for all proposed human research, the Department's human research review committee.

6 VAC 35-170-120. Research Proposals That Do Not Involve Human Research.

Designated Department personnel shall review research proposals that do not involve human research and make a recommendation to the Director within 20 days of the proposal's receipt in the offices of the Department. The Director shall approve or deny proposal within 10 days of receiving the staff recommendation.

6 VAC 35-170-130. Human Research Review Committee

A. In accordance with § 32.1-162.19 of the Code of Virginia, the Department shall establish a human research review committee composed of persons of various backgrounds, to ensure the competent, complete and professional review of human research activities conducted or proposed to be conducted or authorized by the Department. No member of the committee shall be directly involved in the proposed human research or have administrative approval authority over the proposed research except in connection with his role on the committee.

B. The committee may enlist the aid of persons with pertinent expertise and competence to assist in the review of any research proposal or ongoing human research activities.

C. The committee may require additional information from the researcher before making a recommendation to the Director.

6 VAC 35-170-140. Timeline for review of human research proposals.

A. The Human Research Review Committee will review proposals involving human research within 30 days of receiving a complete research proposal.

B. At the request of the researcher, the committee may conduct an expedited review when the proposed research involves no more than minimal risk to the human subjects and:

1. The proposal has been reviewed and approved by another agency's human research review committee; or
2. The review involves only minor changes to a research project that was previously approved.

6 VAC 35-170-150. Committee review of human research proposals.

In reviewing the human research proposal, the committee will consider:
1. The potential benefits and risks to the human subjects, and whether the benefits outweigh the risks;
2. The adequacy of the research methodology;
3. If the research is non-therapeutic, whether it represents more than a minimal risk to the human subjects;
4. whether the rights and welfare of the human subjects are adequately protected;
5. Whether appropriate provisions have been made to obtain informed consent from the human subjects, as detailed in 6 VAC 35-170-160;
6. Whether the researchers are appropriately qualified;
7. Whether the criteria and means for selecting human subjects are valid and equitable; and
8. Whether the research complies with the requirements set out in this regulation and in applicable Department policies and procedures.

6 VAC 35-170-160. Committee review of human research informed consent provisions.

A. The committee shall review and approve the consent process and all required consent forms for each proposed human research project before recommending approval to the Director.

B. The committee may approve a consent procedure which omits or alters some or all of the

basic elements of informed consent, or waives the requirement to obtain informed consent, if the committee finds and documents that:

1. Research involves no more than a minimal risk to the subjects;

2. The omission, alteration or waiver will not adversely affect the rights and welfare of the subjects;

3. The research could not practicably be performed without the omission, alteration or waiver; and

4. After participation, the subjects are to be given additional pertinent information, whenever appropriate.

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

6 VAC 35-170-170. Recommendation to Director and final action.

A. The committee shall make a recommendation to the Director to deny, approve, or conditionally approve the proposed human research.

B. The Director shall approve or deny the proposal within 10 days of receipt of the committee's recommendation.

C. The Research Agreement shall become effective only after all reviews required by this regulation and Department procedures are completed and the Director signs the agreement on behalf of the Department. The coordinator of external research must forward a copy of the signed Research Agreement to the researcher before the project may begin.

6 VAC 35-170-180. Annual Review of human research activities.

The human research review committee shall review all human research activities at least annually to ensure that they are being conducted in conformance with the proposals as recommended by the committee and approved by the Director.

6 VAC 35-170-190. Committee reports required.

The committee 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 committee, and the status of such research, including any significant deviations from the proposals as approved. The report to the board shall also include a summary of human research proposals that were not approved.

6 VAC 35-170-200. Progress reports.

The Department may require periodic reports on the progress of any research project. The principal researcher shall be responsible for providing such reports, and any supplementary information requested by the Department, in a timely manner.

6 VAC 35-170-210. Department permission to use research findings.

The research agreement shall specify that the Department has unrestricted permission to use, as they are published, all data, summaries, charts, graphs or other illustrations resulting from the research project.

6 VAC 35-170-220. Final report.

A. The Department shall require that a formal final report be submitted to the coordinator of external research, and may require up to ten copies of the report.

B. The report shall contain a statement qualifying participation of the Department so as not to imply approval or endorsement of the publication.