COMMONWEALTH of VIRGINIA

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MEMORANDUM

TO: KARIN CLARK
Virginia Department of Social Services

FROM: Jennifer C. Williamson
Senior Assistant Attorney General

DATE: October 12, 2022

SUBJECT: Fast-Track Review of 22 VAC 40-890
Update Human Subject Research Regulations

I am in receipt of and have reviewed the attached regulations, which are being amended to align the regulation with federal regulations and state code, update citations and to make technical changes for clarity. You have asked the Office of the Attorney General to review this action and determine if the State Board of Social Services ("State Board") has the statutory authority to promulgate the proposed regulations and if the proposed regulations comport with applicable state law.

Pursuant to Virginia Code § 63.2-217, the State Board is required to promulgate regulations as may be necessary or desirable to carry out the purposes of Title 63.2 of the Virginia Code. The proposed regulations comport with applicable state law. Further, it is my opinion the State Board has the authority to promulgate these fast-track regulations, subject to compliance with the provisions of Article 2 of the Administrative Process Act ("APA") and Executive Order 19, including the Procedures of the Office of Regulatory Management, and that in so doing the State Board does not exceed that authority.

If you have any questions, please feel free to call me at (804) 225-3197.

Attachment

Project 6069 – Fast Track

Department of Social Services

CH 0890 Update Human Subject Research Chapter

Chapter 890

Human Subject Research Regulations

22VAC40-890-10. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

"Affiliated with the department" means any individual employed, either on a paid or volunteer basis, by the Virginia Department of Social Services, by a local department of social services, or by ~~an agency~~ a facility licensed by the Virginia Department of Social Services.

"Authorized" means to permit the implementation or conducting of research.

~~"Board" means the Virginia State Board of Social Services.~~

"Commissioner" means the Commissioner of the Virginia Department of Social Services or his designee.

"Committee" means the human research review committee, also known as the Institutional Review Board (IRB), which reviews and approves human research activities related to this chapter.

"Contractor" means agencies, organizations, or individuals providing goods or services, receiving funds, or under contract with the department or a local ~~agency~~ department including, but not limited to, foster homes ~~and day-care homes~~.

"Department" means the Virginia Department of Social Services.

"Discomforts, risks, and benefits" means the expected advantages and disadvantages to the participant for participating in the research.

"Facility" means any ~~agency~~ person as defined in Code § 63.2-1701(A) licensed by the department ~~including, but not limited to, adult and child day and residential facilities~~.

"Human participant" or "participant" means any individual, customer, volunteer, or employee who is the subject of research conducted or authorized by the department, facility, local ~~agency~~ department, or contractor.

"Human research" ~~or "research" means any formal and structured evaluation involving individuals in a special project, program, or study~~ means any 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 C.F.R. § 46.104(d).

"Informed consent" means the knowing and voluntary agreement ~~of the participant exercising free choice, without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion.~~, 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. For the purposes of human research, the basic elements of information necessary to such consent shall include:

1. A reasonable and comprehensible explanation to the person of the proposed procedures or 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 appropriate 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 a person with authority to consent on behalf of a prospective participant to include (i) the parent or parents having custody, (ii) the legal guardian, or (iii) any person or judicial or other person or body authorized by law or regulation, including an attorney in fact appointed under a durable power of attorney, to the extent the power grants the authority to make a decision related to human research. The attorney in fact shall not be employed by the person or department conducting the human research. No official or employee of the department, facility or local agency conducting or authorizing the research shall be qualified to act as a legally authorized representative.~~ means, in the following specified order of priority, (i) the parent or parents having custody of a prospective subject who is a minor, (ii) the agent appointed under an advance directive, as defined in § 54.1-2982, executed by the prospective subject, provided the advance directive authorizes the agent to make decisions regarding the prospective subject's participation in human research, (iii) the legal guardian of a prospective subject, (iv) the spouse of the prospective subject, except where a suit for divorce has been filed and the divorce decree is not yet final, (v) an adult child of the prospective subject, (vi) a parent of the prospective subject when the subject is an adult, (vii) an adult brother or sister of the prospective subject or (viii) any person or judicial or other body authorized by law or regulation to consent on behalf of a prospective subject to such subject's participation in the particular human research. For the purposes of this chapter, any person authorized by law or regulation to consent

on behalf of a prospective subject to such subject's participation in the particular human research shall include an attorney in fact appointed under a durable power of attorney, to the extent the power grants the authority to make such a decision. The attorney in fact shall not be employed by the entity conducting the human research. No official or employee of the entity conducting or authorizing the research shall be qualified to act as a legally authorized representative.

"Local department" means the local department of social services of any county or city in this Commonwealth.

"Minimal risk" means that the risks of harm to the prospective participant 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.

22VAC40-890-20. Applicability.

This chapter shall apply to the Virginia Department of Social Services, to local departments of social services ~~or departments of welfare~~, to facilities licensed by the department, and to contractors that authorize, conduct, or propose to conduct or authorize any human research.

22VAC40-890-30. Research exempt from chapter.

Research activities in which the only involvement of human participants will be in one or more of the following categories are exempt from this chapter unless the research is covered by other sections of this chapter:

1. Human research which is subject to policies and regulations for the protection of human subjects promulgated by any agency of the federal government, except for the provisions in 22VAC40-890-40 C and 22VAC40-890-90 B.

2. Research conducted in established or commonly accepted educational settings involving commonly used educational practices, provided that participants cannot be identified, directly or through identifiers, for:

a. Regular and special education instructional strategies;

b. The effectiveness of or the comparison among instructional techniques, curriculum or classroom management methods; or

c. Educational tests.

3. Research involving solely the observation of public behavior or survey or interview procedures, except when observations or responses are recorded in such a manner that participants can be identified directly or through identifiers linked to the participants, and when either (i) the participant's responses, if they became known outside the research, could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing or employability; or (ii) the research deals with sensitive aspects of the participant's own behavior, such as sexual behavior, drug or alcohol use or illegal conduct.

4. Research involving survey or interview procedures, when the respondents are elected or appointed public officials or candidates for public office.

5. Research involving solely the collection or study of existing data, documents, or records, if these sources are publicly available or if the information taken from these sources is recorded in such a manner that participants cannot be identified directly or through identifiers linked to the participants.

6. Research and demonstration projects covered under 45 CFR 46.101(b)(5) which are conducted by or subject to the approval of the commissioner, and which are designed to study, evaluate, or otherwise examine (i) public benefit or service programs; (ii)

~~procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.~~

2. Research involving solely the observation of public behavior or survey or interview procedures, except when observations or responses are recorded in such a manner that participants can be identified directly or through identifiers linked to the participants, and when either (i) the participant's responses, if they became known outside the research, could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing or employability; or (ii) the research deals with sensitive aspects of the participant's own behavior, such as sexual behavior, drug or alcohol use or illegal conduct.

3. Research that is exempt pursuant to 45 CFR § 46.104(d).

22VAC40-890-40. Policy.

A. Each human research activity, as well as significant changes to approved research proposals, shall be submitted to and approved by a committee composed of representatives of varied backgrounds prior to implementation of the research. The committee shall ensure the competent, complete, and professional review of human research activities conducted, authorized, or proposed to be conducted or authorized by the department, local ~~agencies~~ departments, facilities, or ~~contractor~~ contractors. The committee shall ensure the participants' rights to privacy are maintained.

B. Every person engaged in the conduct of human research or proposing to conduct human research shall report to an agency having a research review committee, and the human research which he conducts or proposes to conduct shall be subject to review and approval by such committee in the manner set forth in this chapter.

C. Every person or organization engaged in a human research project that requires an allowable variance or other approval related to department regulations must obtain approval for such from the department prior to requesting the committee's review and approval of the proposed research.

D. Prior to the initiation of any human research, each participant or legally authorized representative must be informed in writing of the following:

1. Procedure or procedures to be utilized, their purposes, and any expected discomforts, risks, and benefits;

2. Instruction that the participant may withdraw his consent and discontinue participation in the human research at any time without loss of services or benefits to which the participant is otherwise entitled;

3. Explanation of any costs or benefits which may accrue to the participant or the participant's family;

4. An offer to answer any inquiries by the participant concerning the procedures and use of the results;

5. Statement assuring confidentiality of records and describing the extent to which confidentiality of records identifying the participant will be maintained; and

6. Expected duration of participation.

E. Where the human research activity exposes ~~to risk~~ risks to others not participating, all must give their signed voluntary informed consent.

F. The committee may suspend or terminate research that is in violation of the research protocol.

22VAC40-890-50. Informed consent.

A. No human research may be conducted without voluntary informed consent signed by the participant or by the participant's legally authorized representative and witnessed, except as provided for in ~~subsection C~~ subsections B and C ~~of this section~~. If the participant is a minor otherwise capable of rendering voluntary informed consent, the consent shall be signed by both the minor and his legally authorized representative. A researcher shall seek such consent only under circumstances that provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the participant or the representative shall be in language understandable to the participant or the representative.

B. The committee may approve a consent procedure which omits or alters basic elements of informed consent or may waive the requirements to obtain informed consent, provided the committee finds and documents that:

1. The research involves no more than minimal risk to the participants;

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

3. The research could not practicably be carried out without the waiver or alteration of the informed consent; and

4. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

C. The committee may waive the requirement for the researcher to obtain a signed consent form for some or all participants if it finds that the only record linking the participant 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 investigator to provide

participants with a written statement explaining the research. Each participant shall be asked whether he wants documentation linking him to the research and the subject's wishes shall govern.

22VAC40-890-60. Human research review committee.

A. The department shall establish a department committee, consisting of ~~seven~~ at least five members, appointed by the commissioner. The department committee is authorized (i) to determine if a proposed project is human subject research; and (ii) to review and approve any human research proposed, authorized, or conducted by the department, by any local ~~agency~~ department, by any facility, or by any contractor.

B. All human research conducted or authorized by the department, any local ~~agency~~ department, any facility, or any contractor must be reviewed and approved by the department committee, except local ~~agencies,~~ departments, facilities, or contractors collaborating with another organization on a research project may instead elect to utilize that organization's research review committee.

C. Members of the committee will be appointed to ensure the competent, complete, and professional review of human research. No member of the committee shall be directly involved in the proposed human research project or have administrative approval authority over the proposed research, except in connection with his responsibilities as a member of the committee. At least two members of the committee must be individuals whose primary concerns are in nonscientific or ethical areas (e.g., the clergy, lawyers).

D. The committee shall include at least two members who are not affiliated with and are not immediate family members of persons who are affiliated with the department.

E. No member of the committee shall participate in the committee's initial or continuing review of any project in which the member has a conflicting interest, except to provide information

requested by the committee. The committee has responsibility for determining whether a member has a conflict of interest. If necessary, the committee size shall be maintained by the appointment of a substitute representative to review a project where a member has a conflicting interest.

F. A committee may, at its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the committee. These individuals may not vote with the committee.

G. A quorum of the committee shall consist of a majority of its members.

H. The committee shall establish procedures and rules of operations necessary to fulfill the requirements of this chapter.

22VAC40-890-70. Review and approval process.

A. Prior to the initiation of a human research project, a description of the proposed human research project shall be submitted to the department committee for review and approval, except for projects which are exempt or those reviewed by another organization's committee. The description shall include a statement of the purpose of the proposed project and justification of it, the criteria for inclusion of a participant in the research project, a description of what will be done to the participants, and the proposed informed consent statement.

B. No human research shall be conducted or authorized by the department unless the department committee has reviewed and approved the proposed human research project giving consideration to:

1. The necessity and utility of the research;

2. The adequacy of the description of potential benefits and risks involved and the appropriateness of the research methodology;

3. Whether the research presents more than a minimal risk to the subject;

4. Whether the risks to the participants are outweighed by the potential benefits to them;

5. Whether the rights and welfare of the participants involved are adequately protected;

6. Whether the voluntary informed consent is obtained by methods (including the written consent form) that are adequate and appropriate considering the participants' educational level and language of greatest fluency;

7. Whether the people proposing to supervise or conduct the research are competent and qualified; and

8. Whether the criteria for selection of participants is equitable.

C. Except for the research referenced in 22VAC40-890-80, the committee shall consider research proposals within 30 days after submission to the committee. In order for the research to be approved, it shall receive the approval of a majority of those members present at a meeting in which a quorum exists. The committee shall notify investigators in writing of its decision to approve or disapprove the proposed research activity or of modifications required to secure committee approval.

D. During the committee review of research projects, no personal identifiers of present or potential participants shall be presented or discussed.

E. The committee shall require a written description of the procedure to be followed when a participant has a complaint about a research project in which he is participating or has participated. All complaints shall be referred to the committee to determine if there has been a violation of the established protocol.

F. The committee shall require reports from approved research projects at least annually to ensure conformity with the approved proposal. The frequency of such reports shall be consistent with the nature and degree of risk of each research project. The committee shall also require a

report from the research project at the conclusion of the project. Continuing review of research is not required in the following circumstances:

1. Research eligible for expedited review in accordance with 22VAC40-890-80; or

2. Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:

a. Data analysis, including analysis of identifiable private information or identifiable biospecimens; or

b. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

22VAC40-890-80. Expedited review of human research participants.

A. The committee is authorized to conduct an expedited review of a human research project which involves no more than minimal risk to the participants if:

~~1. The~~ the research review committee affiliated with another state department, local ~~agency~~ department, licensed facility, or institution has reviewed and approved the project; ~~or~~

~~2. The review involves only minor changes in previously approved research and the changes occur during the approved project period~~.

B. In accordance with 45 CFR § 46.110, as determined by the U.S. Secretary of Health and Human Services (HHS) and published as a Notice in the Federal Register, certain categories of research may be reviewed by the IRB through an expedited review procedure. The Secretary of HHS will evaluate the list at least every eight years and amend it, as appropriate. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.

C. The IRB may use the expedited review procedure to review the following:

1. Some or all of the research appearing on the list described in subsection B, unless the reviewer determines that the study involves more than minimal risk; or

2. Minor changes in previously approved research during the period for which approval is authorized.

D. Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the nonexpedited procedure set forth in 22VAC40-890-70.

E. The committee shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

F. The expedited review procedure may not be used where identification of the subjects or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

22VAC40-890-90. Reporting.

A. The department's research review committee shall report by December 15 of each year to the commissioner on activities of the committee during the year. The report shall include:

1. A description of each human research project reviewed and whether approved or disapproved;

2. Any significant changes from research proposals as approved by the committee;

3. A list of committee members, their qualifications for service on the committee, and their affiliation with the department, local agency, or facility;

4. A copy of the minutes of each committee meeting; and

5. Results of the research after its conclusion.

B. A local ~~agency~~ department, facility or contractor participating in a human subject research project reviewed by another ~~agency's~~ research review committee shall report to the department research review committee by December 1 of each year on such participation. The report shall include:

1. A description of each human research project in which the ~~agency participated;~~ local department, facility or contractor, including the name and contact information for the approving research review committee participated; and

2. Results of the research after its conclusion~~.~~, including a description of how the research will be shared beyond the local department, facility or contractor.

C. The chairperson of the department's committee shall report as soon as possible to the commissioner any violation of the research protocol that may lead the committee to either suspend or terminate the research.

D. The commissioner shall report at least annually to the Governor and General Assembly on the human research projects authorized or conducted by the department, local ~~agency~~ department, facility, or contractor.

E. Other reports may be required by the committee, as indicated in 22VAC40-890-70 F.

22VAC40-890-100. Committee records.

A. Documentation of all committee activities shall be prepared and maintained and shall include the following:

1. Copies of all research documents, including proposals reviewed, evaluations that may accompany the proposals, approved sample consent documents, progress reports submitted by researchers, reports of injuries to participants, and correspondence related to the research project;

2. Minutes of committee meetings which shall be in sufficient detail to show attendance; actions taken by the committee; the vote on these actions, including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research and a summary of the discussion of controversial issues and their resolution;

3. Records of continuing review activities;

4. A list of committee members; and

5. Written procedures for the committee.