

I. Purpose:

This guidance document addresses Commonwealth of Virginia laws relating to “human research” activities and their applicability to the Virginia Department of Social Services (VDSS) Institutional Review Board (IRB). For purposes of this guidance, the terms “human research” and “human subjects research” are interchangeable.

- A. Federal regulations pertaining to human subjects research state explicitly they do not affect state laws which may otherwise be applicable and which provide additional protections for human subjects.¹
- B. The Code of Virginia states “Human research which is subject to policies and regulations for the protection of human subjects promulgated by any agency of the federal government shall be exempt from the provisions of this chapter”.²

II. Scope of guidance document

This guidance applies to all on-going and future human research projects conducted, authorized or supported by VDSS, local departments of social services (LDSS), VDSS contractors, VDSS licensed facility or by anyone conducting a research activity supported by VDSS, LDSS, VDSS licensed facility or VDSS contractor, or where VDSS, LDSS, VDSS licensed facility or VDSS contractor is considered to be engaged in the research.

III. Commonwealth of Virginia Laws Addressing VDSS Human Research Issues

- A. Code of Virginia Section 63.2-218; the Board to adopt regulations regarding human research
- B. Code of Virginia Section 32.1-162.16 et seq.; Human Research
- C. 22VAC40-890-100 et seq.; VDSS Administrative Code for human research.

IV. Terms and Definitions

- A. "Guidance document" means any document developed by a state agency or staff that provides information or guidance of general applicability to the staff or public to interpret or implement statutes or the agency's rules or regulations, excluding agency minutes or documents that pertain only to the internal management of agencies. Nothing in this definition shall be construed or interpreted to expand the identification or release of any document otherwise protected by law.³
- B. "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

¹ 45 CFR § 46.101(f)

² Code of Virginia 32.1-162.20

³ Code of Virginia Section 2.2-4001

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 person, institution, or agency conducting the human research. **No official or employee of the institution or agency conducting or authorizing the research shall be qualified to act as a legally authorized representative.**⁴

- C. Conducting or authorizing research means engagement⁵ in human subjects research activities.
- D. See the Virginia Administrative Code, 22VAC40-890-10, for definitions of other VDSS IRB terms.

V. Issues of Informed consent

In order to conduct human research in this Commonwealth, informed consent must be obtained if the person who is to be the human subject is as follows: (i) capable of making an informed decision, then it shall be subscribed to in writing by the person and witnessed; (ii) incapable of making an informed decision, as defined in § 54.1-2982, at the time consent is required, then it shall be subscribed to in writing by the person's legally authorized representative and witnessed; or (iii) a minor otherwise capable of rendering informed consent, then it shall be subscribed to in writing by both the minor and his legally authorized representative.⁶

- A. Under the federal Common Rule, “children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted”⁷ In the Commonwealth of Virginia, a person shall be an adult, shall be of full age, and shall reach the age of majority when he becomes 18 years of age.⁸
- B. When VDSS or an LDSS conducts or authorizes human research, no official or employee of the institution or agency conducting or authorizing the research shall be qualified to act as a legally authorized representative (See above definition of legally authorized representative).

⁴ Code of Virginia §32.1-162.16

⁵ OHRP Engagement of Institutions in Human Subjects Research 2008

⁶ Code of Virginia §32.1-162.18A

⁷ 45 CFR 46.402

⁸ Code of Virginia §1-204 Age of Majority

Commonwealth of Virginia Laws Relevant to Human Subjects Research and Informed Consent

- C. “Where the human research activity exposes to risk others not participating, all must give their signed voluntary informed consent.”⁹
- D. Notwithstanding consent by a legally authorized representative, no person shall be forced to participate in any human research if the investigator conducting the human research knows that participation in the research is protested by the prospective subject.¹⁰
- E. A legally authorized representative may not consent to participation in human research on behalf of a prospective subject if the legally authorized representative knows, or upon reasonable inquiry ought to know, that any aspect of the human research protocol is contrary to the religious beliefs or basic values of the prospective subject, whether expressed orally or in writing.¹¹
- F. Foster Care children and youth cannot participate as research subjects when the Virginia Department of Social Services (VDSS) and/or Local departments of social services (LDSS) are conducting or authorizing the research study. Such participation would constitute a conflict of interest for VDSS and/or LDSS because of their legal relationship to foster care children and youth as LAR¹².

⁹ 22VAC40-890-40E

¹⁰ Code of Virginia §32.1-162.18A

¹¹ Code of Virginia §32.1-162.18B

¹² Reference: October 4, 2016 telephone conversation between Jennifer Williamson, Office of the Attorney General, and Myra G. Owens, PhD, Chairperson/Administrator VDSS IRB. Also see E-mail W:\Strategy_Management\Institutional Review Board\Policies and Operating Procedures\VDSS Guidance Documents\October 2016 EMail COI VDSS and LDSS research and foster care children.pdf