

Virginia Laws on Human Subjects Research and Informed Consent

I. Purpose

This guidance covers Virginia laws on “human research” and their applicability to VDSS IRB. “Human research” and “human subjects research” are interchangeable.

- A. Federal regulations do not affect applicable state laws providing additional protections.¹
- B. Virginia Code states human research subject to federal agency policies is exempt from this chapter.²

II. Scope

This guidance applies to all ongoing and future human research conducted, authorized, or supported by VDSS, LDSS, contractors, licensed facilities, or where VDSS or affiliates are engaged.

III. Virginia Laws Addressing VDSS Human Research Issues

- [Virginia Code §63.2-218](#); Board to adopt human research regulations
- [Virginia Code §32.1-162.16 et seq.](#); Human Research
- [22VAC40-890-10 et seq.](#); VDSS Administrative Code for human research.

IV. Terms and Definitions

¹ [45 CFR §46.101\(f\)](#)

² [Virginia Code §32.1-162.20](#)

- 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 the prospective subject, (iv) spouse, except Commonwealth of Virginia Laws Relevant to Human Subjects Research and Informed Consent 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.**³

- B. "Conducting or authorizing research" means engagement in human subjects research activities.

See the Virginia Administrative Code, [22VAC40-890-10](#), for definitions of other VDSS IRB terms.

V. Informed Consent

Human research requires informed consent in writing if the subject is as follows: (i) capable of making an informed decision, in which case consent must be obtained from the person and witnessed; (ii) incapable of making an informed decision, in which case consent must be obtained by a legally authorized representative and witnessed; or (iii) a minor capable of consent, in which case consent must be obtained from the minor and his/her legal guardian.⁴

³ Virginia Code §[32.1-162.16](#)

⁴ Virginia Code §[32.1-162.18](#)

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- A. Under the federal Common Rule, children are persons under the legal age for consent in the jurisdiction.⁵ In Virginia, a person is an adult at age 18.⁶
- 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.)
- C. If research exposes others to risk, all must give signed voluntary informed consent.⁷
- D. Despite a legally authorized representative's consent, no one shall be forced to participate if the investigator knows the person protests participation.⁸
- E. A legally authorized representative cannot consent if they know or should know the protocol conflicts with the prospective subject's religious beliefs or values, whether expressed orally or in writing.⁹
- F. Foster care children cannot participate in research conducted or authorized by VDSS and/or LDSS. This constitutes a conflict of interest for VDSS/LDSS due to their legal role as a legally authorized representative for foster children.¹⁰

⁵ [45 CFR 46.402](#)

⁶ Virginia Code [§1-204](#) (Age of Majority)

⁷ [22VAC40-890-40E](#)

⁸ Code of Virginia [§32.1-162.18A](#)

⁹ Code of Virginia [§32.1-162.18B](#)

¹⁰ Telephone conversation between Jennifer Williamson, Office of the Attorney General, and Myra G. Owens, PhD, VDSS IRB Chairperson/Administrator on October 4, 2016.