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HOUSE BILL NO. 930

Offered January 12, 2022

Prefiled January 12, 2022

A BILL to amend and reenact § 32.1-162.16 of the Code of Virginia and to amend the Code of Virginia by adding in Chapter 5.1 of Title 32.1 a section numbered 32.1-162.20:1, relating to human research; research involving minors; requirements.

Patron—Robinson

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That § 32.1-162.16 of the Code of Virginia is amended and reenacted and that the Code of Virginia is amended by adding in Chapter 5.1 of Title 32.1 a section numbered 32.1-162.20:1 as follows:

§ 32.1-162.16. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Human research" 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. § 46.101(b).

"Human subject" means the same as such term is defined in 45 C.F.R. § 46.102.

"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 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.

"Institution" or "agency" means any facility, program, or organization owned or operated by the Commonwealth, by any political subdivision, or by any person, firm, corporation, association, or other legal entity.

"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 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.

"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.

"Nontherapeutic research" means human research in which there is no reasonable expectation of direct benefit to the physical or mental condition of the human subject.

§ 32.1-162.20:1. Human research involving minors.

A. Any person conducting human research in which a minor is a human subject shall comply with all applicable federal and state laws and regulations.

B. All human research involving a minor as a human subject shall be subject to review by an institutional review board established in accordance with Part 46 of Chapter 45 of the Code of Federal Regulations that is not affiliated with the institution or agency at which the research is proposed to be conducted prior to initiation of such research, and, notwithstanding the provisions of 45 C.F.R. § 46.104, no human research involving a minor as a human subject shall be exempt from review by an institutional review board. The recommendations of an institutional review board that reviews proposed human research involving a minor as a human subject shall be binding, and no person shall conduct human research involving a minor as a human subject if such research is not approved by an institutional review board.

C. Notwithstanding federal law and regulation to the contrary, ongoing human research projects that involve a minor as a human subject shall be subject to continuing review by the institutional review board that conducted the initial review of the human research project. Continuing review shall be performed at least annually. However, ongoing human research involving a minor as a human subject shall not be eligible for continuing review if more than five years have elapsed from the date on which the human research was initially approved, and ongoing human research projects shall be subject to initial review by the institutional review board at least once every five years.

D. No human research involving a minor as a human subject shall be performed until the minor's parent or guardian has provided informed written consent to such research. No institutional review board may waive the requirement for parental consent required by this subsection.

E. Records related to institutional review board reviews of human research involving a minor as a human subject, including (i) a list of institutional review board members, (ii) written procedures applicable to such reviews, (iii) copies of research proposals reviewed by the institutional review board, (iv) minutes of institutional review board meetings, and (v) records of continuing review activities conducted by the institutional review board, shall be made available to the public on a website maintained by the institution at which the human research is conducted and on a website maintained by the institution with which the institutional review board is affiliated.