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SENATE BILL NO. 542

Offered January 9, 2002

Prefiled January 9, 2002

A BILL to amend and reenact §§ 32.1-162.16 and 32.1-162.18 of the Code of Virginia, relating to human research; definitions.

Patrons—Mims; Delegate: Reese

Referred to Committee for Courts of Justice

Be it enacted by the General Assembly of Virginia:

1. That §§ 32.1-162.16 and 32.162.18 of the Code of Virginia are amended and reenacted 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 utilizing human subjects ~~which~~ *that* may expose such human subjects to physical or psychological injury as a consequence of participation as subjects and ~~which~~ *that* departs from the application of established and accepted therapeutic methods appropriate to meet the subjects' 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 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,* (~~ii~~ *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 non-custodial parent of the prospective subject who is an adult, (vii) an adult brother or sister of the prospective subject* or ~~(iii)~~ *(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. *If two or more of the persons listed in clauses (i) through (viii), with equal decision-making priority, inform the principal investigator or attending physician that they disagree as to participation of the prospective subject in human research, the principle investigator or attending physician may rely on the authorization of a majority of the reasonably available members of that class.* 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.

§ 32.1-162.18. Informed consent.

A. 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) ~~competent~~ *capable of making an informed decision,* then it shall be subscribed to in writing by the person and witnessed; (ii) ~~not competent~~ *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. The giving of consent by a legally authorized representative shall be subject to the provisions of subsection B of this section. No informed consent form shall include any language through which the person who is to be the human subject waives or appears to waive any of his legal rights, including any release of any individual, institution, or agency or any agents thereof from liability for negligence.

Notwithstanding consent by a legally authorized representative, no person who is otherwise capable of rendering informed consent shall be forced to participate in any human research. In the case of persons suffering from organic brain diseases causing progressive deterioration of cognition for which there is no known cure or medically accepted treatment, the implementation of experimental courses of therapeutic treatment to which a legally authorized representative has given informed consent shall not constitute the use of force.

B. A legally authorized representative may not consent to nontherapeutic research unless it is determined by the human research committee that such nontherapeutic research will present no more than a minor increase over minimal risk to the human subject.

C. The human research review 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 (i) the research involves no more than minimal risk to the subjects; (ii) the omission, alteration or waiver will not adversely affect the rights and welfare of the subjects; (iii) the research could not practicably be performed without the omission, alteration or waiver; and (iv) after participation, the subjects are to be provided with additional pertinent information, whenever appropriate.

D. The human research review committee may waive the requirement that the investigator obtain written informed consent for some or all subjects, if the committee finds that 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 investigator to provide the subjects with 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.