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SENATE BILL NO. 542

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the Senate Committee for Courts of Justice on February 10, 2002)

(Patron Prior to Substitute—Senator Mims)

A BILL to amend and reenact §§ 32.1-162.16, 32.1-162.18 and 32.1-162.19 of the Code of Virginia, relating to human research; definitions.

Be it enacted by the General Assembly of Virginia:

1. That §§ 32.1-162.16, 32.1-162.18 and 32.1-162.19 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, *including research development, testing and evaluation,* utilizing human subjects ~~which may expose such human subjects to physical or psychological injury as a consequence of participation as subjects and which departs from the application of established and accepted therapeutic methods appropriate to meet the subjects' needs~~ *designed to develop or contribute to generalized knowledge. Human research shall not be deemed to include research exempt from federal research regulation pursuant to 42 C.F.R § 46.101(b).*

"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 parent of the prospective subject when the subject 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. 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. *If two or more persons who qualify as legally authorized representatives and have equal decision-making priority under this chapter inform the principal investigator or attending physician that they disagree as to participation of the prospective subject in human research, the subject shall not be enrolled in the human research that is the subject of the consent.* 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 *if the investigator conducting the human research knows that participation in the research is protested by the prospective subject*. 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. *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. A legally authorized representative may not consent to participation in human research involving nontherapeutic sterilization, abortion, psychosurgery or admission to a facility or hospital as defined in § 37.1-1.*

C. *Except as provided elsewhere in this chapter, no investigator may involve a human being as a subject in research covered by this chapter unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.*

D. 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~~ *E.* 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.

§ 32.1-162.19. Human research review committees.

A. Each institution or agency which conducts or which proposes to conduct or authorize human research shall establish a human research review committee. The committee shall be composed of representatives of varied backgrounds to ensure the competent, complete, and professional review of human research activities conducted or proposed to be conducted or authorized by the institution or agency. No member of the committee shall be directly involved in the proposed human research or have administrative approval authority over the proposed human research except in connection with his responsibilities as a member of the committee.

B. No human research shall be conducted or authorized by such institution or agency unless the committee has reviewed and approved the proposed human research project giving consideration to (i) the adequacy of the description of the potential benefits and risks involved and the adequacy of the methodology of the research; (ii) if the research is nontherapeutic, whether it presents more than a minimal risk to the human subjects; (iii) whether the rights and welfare of the human subjects involved

are adequately protected; (iv) whether the risks to the human subjects are outweighed by the potential benefits to them; (v) *whether the risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk and, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes; (vi) when some or all of the subjects are likely to be incapable of making an informed decision regarding consent or are otherwise vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, whether additional safeguards have been included in the study to protect the rights and welfare of these subjects; (vii)* whether the informed consent is to be obtained by methods that are adequate and appropriate and whether the written consent form is adequate and appropriate in both content and language for the particular research; (vi*ii*) whether the persons proposing to conduct the particular human research are appropriately competent and qualified; and (~~vii~~ *ix*) whether the criteria for selection of subjects are equitable. The committee shall require periodic reports from each existing human research project to ensure that the project is being carried out in conformity with the proposal as approved.

C. The regulations of an institution or agency may authorize the committee to conduct an expedited review of a human research project which involves no more than minimal risk to the subjects if (i) another institution's or agency's human research review committee has reviewed and approved the project or (ii) the review involves only minor changes in previously approved research and the changes occur during the approved project period.

D. Every person engaged in the conduct of human research or proposing to conduct human research shall affiliate himself with an institution or 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 section.