VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact § 32.1-162.18 of the Code of Virginia, relating to informed consent to experimental treatment; neurodegenerative diseases.

[H 337]

Approved

Be it enacted by the General Assembly of Virginia:

1. That § 32.1-162.18 of the Code of Virginia is amended and reenacted as follows:

§ 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) 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. 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 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~~ *neurodegenerative 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, *including non-pharmacological 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 for research purposes to a facility or hospital as defined in § 37.2-100.

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.

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.