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HOUSE BILL NO. 639

Offered January 9, 2002
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A BILL to amend and reenact §§ 32.1-162.16, 32.1-162.19, 32.1-162.20, and 32.1-289.1 of the Code of Virginia, relating to human embryonic stem cell research; penalty.

Patron—O'Brien

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That §§ 32.1-162.16, 32.1-162.19, 32.1-162.20, and 32.1-289.1 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 embryonic stem cell" means an early cell of the blastocyst proper that has the potential to differentiate into various specialized human cell types.

"Human research" means any systematic investigation 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.

"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 (i) the parent or parents having custody of a prospective subject, (ii) the legal guardian of a prospective subject, or (iii) 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.

§ 32.1-162.19. 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 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) whether the persons proposing to conduct the particular human research are appropriately competent and qualified; and (vii) 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.

E. No human research review committee shall approve any project involving, in any way, the harvesting of human embryonic stem cells from human embryos or pre-embryos that were created for the purpose of conducting research, regardless of the funding or purpose of such project. This prohibition shall not be interpreted to apply to federally approved human embryonic stem cell research or to research involving adult human stem cells.

§ 32.1-162.20. Applicability of federal policies.

Human research which is subject to policies and regulations for the protection of human subjects promulgated by any agency of the federal government shall be exempt from the provisions of this chapter. *However, projects involving the harvesting of human embryonic stem cells from human embryos or pre-embryos that were created for the purpose of conducting research shall be subject to the provisions of this chapter, regardless of the funding or purpose of such project.*

In lieu of promulgating regulations pursuant to the requirements of this chapter, an institution or agency may comply with this chapter by promulgating regulations under the provisions of the Administrative Process Act (§ 2.2-4000 et seq.) governing human research projects which incorporate, explicitly or by reference, federal policies and regulations for the protection of human subjects. However, in the case of projects which are not required, by reason of their nature, the source of their funding, or the lack thereof, to comply with federal policies and regulations, the institution or agency *or any person* may enforce compliance *with this chapter or the relevant regulations* by filing a petition for an injunction in the appropriate circuit court. This section shall not preclude any other enforcement action available to the institution or agency.

§ 32.1-289.1. Sale of body parts prohibited; exceptions; penalty.

With the exception of hair, ova, *sperm,* blood, and other self-replicating body fluids, it shall be unlawful for any person to sell, to offer to sell, to buy, to offer to buy, or to procure through purchase any natural body part for any reason including, but not limited to, medical and scientific uses such as transplantation, implantation, infusion, or injection. ~~Nothing~~ ~~in~~ ~~this~~ *This* section shall *not* prohibit the reimbursement of expenses associated with the removal and preservation of any natural body parts for medical and scientific purposes, *except as provided herein*. This section shall not apply to any transaction pursuant to Article 3 (§ 32.1-298 et seq.) of Chapter 8 of this title. *However, the sale or purchase of ova or sperm or the reimbursement for the removal and preservation of ova for the purpose of creating human embryos or pre-embryos for scientific research shall be prohibited.*

Any person engaging in any of these prohibited activities shall be guilty of a Class 6 felony.

2. That the provisions of this act may result in a net increase in periods of imprisonment or commitment. Pursuant to § 30-19.1:4, the estimated amount of the necessary appropriation cannot be determined for periods of imprisonment in state adult correctional facilities and is $0 for periods of commitment to the custody of the Department of Juvenile Justice.