

New York State Consolidated Law: Public Health

ARTICLE 24-A

PROTECTION OF HUMAN SUBJECTS

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Sec. 2440. Policy and purpose. The use of human subjects in medical research projects has brought about many beneficial scientific advances resulting in the increased health and well-being of the human race. Safeguarding the rights and welfare of individual human subjects in the conduct of these human research projects is a matter of vital state concern. Every human being has the right to be protected against the possible conduct of medical or psychological research upon his body without his voluntary informed consent. Human research may effect dangerous and unanticipated results causing irreversible damage to the human subject. Accordingly, it shall be the policy of this state to protect its people against the unnecessary and improper risk of pain, suffering or injury resulting from human research conducted without their knowledge or consent.

Sec. 2441. Definitions. For the purposes of this article:

1. "Human subject" shall mean any individual who may be exposed to the possibility of injury, including physical, psychological or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those established and accepted methods necessary to meet his needs or which increases the ordinary risk of daily life including the reecognized risks inherent in a chosen occupation or field of service.

2. "Human research" means any medical experiments, research, or scientific or psychological investigation, which utilizes human subjects and which involves physical or psychological intervention by the researcher upon the body of the subject and which is not required for the purposes of obtaining information for the diagnosis, prevention, or treatment of disease or the assessment of medical condition for the direct benefit of the subject. Human research shall not, however, be construed to mean the conduct of biological studies exclusively utilizing tissue or fluids after their removal or withdrawal from a human subject in the course of standard medical practice, or to include epidemiological investigations.

3. "Fluid" means a normal body excretion or any fluid formed by normal or pathological body processes obtained during diagnostic or therapeutic procedures conducted for the benefit of the human subject.

4. "Tissue" means part or all of any organ of a human subject removed during a diagnostic or therapeutic procedure

conducted for the benefit of the human subject.

5. "Voluntary informed consent" means the legally effective knowing consent of an individual or his legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress or other form of constraint or coercion. With regard to the conduct of human research, the basic elements of information necessary to such consent include:

(a) a fair explanation to the individual of the procedures to be followed, and their purposes, including identification of any procedures which are experimental;

(b) a description of any attendant discomforts and risks reasonably to be expected;

(c) a description of any benefits reasonably to be expected;

(d) a disclosure of any appropriate alternative procedures that might be advantageous for the individual;

(e) an offer to answer any inquiries by the individual concerning the procedures; and

(f) an instruction that the individual is free to withdraw his consent and to discontinue participation in the human research at any time without prejudice to him.

6. "Researcher" means any person licensed under title VIII of the education law to perform diagnosis, treatment, medical services, prescription or therapeutic exercises with regard to or upon human beings, or any other person deemed appropriately competent and qualified by a human research review committee as provided by section twenty-four hundred forty-four of this chapter.

Sec. 2442. Informed consent. No human research may be conducted in this state in the absence of the voluntary informed consent subscribed to in writing by the human subject. If the human subject be a minor, such consent shall be subscribed to in writing by the minor's parent or legal guardian. If the human subject be otherwise legally unable to render consent, such consent shall be subscribed to in writing by such other person as may be legally empowered to act on behalf of the human subject. No such voluntary informed consent shall include any language through which 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.

Sec. 2443. Conduct of human research. No one except a researcher shall conduct human research in this state.

Sec. 2444. Human research review committees. 1. Each **public** or private institution or agency which conducts, or which proposes to conduct or authorize, human research, shall establish a human research review committee. Such committee shall be composed of not less than five persons, approved by the commissioner, who have such varied backgrounds as to assure 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 a committee shall be involved in either the initial or continuing review of an activity in which he has a conflicting interest, except to

provide information required by the committee. No committee shall consist entirely of persons who are officers, employees, or agents of, or who are otherwise associated with the institution or agency, apart from their membership on the committee, and no committee shall consist entirely of members of a single professional group.

2. The human research review committee in each institution or agency shall require that institution or agency to promulgate a statement of principle and policy in regard to the rights and welfare of human subjects in the conduct of human research, and the committee and the commissioner shall approve that statement prior to its taking effect. The committee shall review each proposed human research project to determine (1) its necessity; (2) that the rights and welfare of the human subjects involved are adequately protected, (3) that the risks to the human subjects are outweighed by the potential benefits to them or by the importance of the knowledge to be gained; (4) that the voluntary informed consent is to be obtained by methods that are adequate and appropriate, and (5) that the persons proposed to conduct the particular medical research are appropriately competent and qualified. The committee shall periodically examine each existing human research project with regard to the proper application of the approved principles and policies which the institution or agency has promulgated. The committee shall report any violation to the commissioner. In addition to the voluntary informed consent of the proposed human subject as required by section twenty-four hundred forty-two of this chapter, the consent of the committee and the commissioner shall be required with relation to the conduct of human research involving minors, incompetent persons, mentally disabled persons and prisoners.

3. Each person engaged in the conduct of human research or proposing to conduct human research shall affiliate himself with an institution or agency having a human research review committee, and such human research as he conducts or proposes to conduct shall be subject to review by such committee in the manner set forth in this section.

Sec. 2445. Applicability. The provisions of this article shall not apply to the conduct of human research which is subject to, and which is in compliance with, policies and regulations promulgated by any agency of the federal government for the protection of human subjects.

Sec. 2446. Rules and regulations. The commissioner shall have the power to promulgate such rules and regulations as shall be necessary and proper to effectuate the purposes of this article.