§ 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.