# STATE OF NEW YORK

2409

2019-2020 Regular Sessions

# IN ASSEMBLY

January 22, 2019

Introduced by M. of A. DICKENS -- read once and referred to the Committee on Health

AN ACT to amend the public health law, in relation to human research

**The People of the State of New York, represented in Senate and Assembly, do enact as follows:**

Section 1. Section 2441 of the public health law is amended by adding ten new subdivisions 7, 8, 9, 10, 11, 12, 13, 14, 15 and 16 to read as follows:

**7. "Minimal risk" means the risks of harm anticipated in the proposed human 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.**

**8. "Greater than minimal risk" means that the risks of harm anticipated in the proposed human research exceed the risks of harm associated with minimal risk human research.**

**9. "Possibly therapeutic human research" is human research which a human research review committee has determined holds out a prospect of direct benefit and is important to the health or well being of the patient and is only available in the context of the human research to be conducted.**

**10. "Non-therapeutic human research" is all human research which is not possibly therapeutic human research.**

**11. "Mental disorder that may affect decision making capacity" means any disorder that alters mental activity, including but not limited to, mental retardation, dementia, bipolar disorder, substance abuse disorder, and any other condition or behavior that calls a person's decision making capacity into question.**

**12. "Research advance directive" means a written advance directive, executed by an individual with the capacity to do so, that states a desire of the individual to participate in research in specific risk/benefit categories.**

**13. "Research agent" means a legally authorized representative to whom authority to make research decisions is delegated under a research**

EXPLANATION--Matter in *italics* (underscored) is new; matter in brackets [-] is old law to be omitted.

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advance directive expressly authorizing participation in research in specific risk/benefit categories.

14. "Assent" means affirmative agreement to participate in research. Mere failure to object does not constitute assent.

15. "Adult" means (a) a person over the age of eighteen years and (b) a person under the age of eighteen years who is (i) in a psychiatric facility on voluntary status on his or her own application, (ii) married or (iii) the parent of a child.

16. "Child" means a person under the age of eighteen who is not an adult as defined herein.

§ 2. Section 2442 of the public health law, as added by chapter 450 of the laws of 1975, is amended to read as follows:

§ 2442. Informed consent. 1. 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 or her legal rights, including any release of any individual, institution or agency, or any agents thereof, from liability for negligence.

2. Any adult person who is determined to lack capacity to provide voluntary informed consent to human research shall be informed of the following if it is proposed to nevertheless use such person as a human subject: (a) that he or she has been found to lack capacity to make a decision regarding the research; (b) of the right to object to any human research he or she may be placed in; (c) of the right to appeal a finding of an incapacity to make a decision; (d) of the availability of legal counsel to assist in appealing a finding of such incapacity; (e) whether the proposed human research is possibly therapeutic or non-therapeutic; (f) the information described in subdivision five of section twenty-four hundred forty-one of this article; (g) the identity of the person who is proposed to act as a surrogate decision maker; and (h) the availability of legal counsel to challenge the identity of the surrogate decision maker.

§ 3. Section 2444 of the public health law, as added by chapter 450 of the laws of 1975, is amended to read as follows:

§ 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 or she 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. When the human research review committee reviews human research involving subjects with mental disorders that may affect decision making capacity, fifteen percent of the committee members, but no

less than one member, must be a person with such a disorder or a family member of such person, or a representative of an advocacy organization concerned with the welfare of such persons. When the human research review committee reviews human research in which race, ethnicity or sex is proposed to be a factor affecting either inclusion or exclusion from human research, at least fifteen percent of the committee members, but no less than one, must be a member of the race, ethnicity or sex which is proposed to be included or excluded.

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~~] article, 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~~] subjects with mental disorders that may affect decision making capacity and prisoners. All documents related to requests seeking the consent of the commissioner to conduct human research on minors, subjects with mental disorders that may affect decision making capacity, and prisoners, and the commissioner's ruling on such requests, shall be made available to the public upon reasonable request, provided that the commissioner may redact proprietary information and trade secrets. The nature of the risks and the nature of the procedures which are proposed to be conducted shall not be considered to be proprietary information or a trade secret.

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

4. No institution or agency shall retaliate against any member of its human research review committee for any action taken by the committee member in connection with his or her work on the committee which may or may not have had adverse effects on the research entity and any of its protocols. Any such aggrieved person may commence an action pursuant to the provisions of this article as if such aggrieved person were a human subject for the purposes of commencing such an action.

§ 4. Section 2445 of the public health law, as added by chapter 450 of the laws of 1975, is amended to read as follows:

§ 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~~] conducted within the state of New York.

§ 5. The public health law is amended by adding six new sections 2447, 2448, 2449, 2450, 2451 and 2452 to read as follows:

§ 2447. Exclusion or inclusion of subjects to participate in human research based on race, ethnicity or sex. 1. When race, ethnicity or sex is proposed to be a factor affecting either inclusion or exclusion from human research, the entity proposing such research protocol shall be provided to the commissioner, with specificity, the criteria and the reasons why it is necessary to include or exclude members of a particular race, ethnic or sexual population, which shall include the goals of such research.

2. No such human research shall be conducted unless it is demonstrated that such research is necessary and that such research is the only manner by which the sought after information may be obtained. The approval of the commissioner shall only be granted upon the submission of such proof. All requests presented to the commissioner seeking such approval shall be published in the state register sixty days prior to the commissioner making a decision about such request.

3. This section will not apply to any human research which attempts to enroll subjects based on race, ethnicity or sex when such enrollment is an attempt to produce the numerical representation of these races, ethnicities or sexes in the general population of this state in particular or the United States in general.

§ 2448. Collection of data. On the first business day of March, on an annual basis, all entities conducting human research shall file with the commissioner the following information relative to all human research conducted in this state in the immediately preceding calendar year:

1. an abstract of each human research protocol which shall include a description of the hypothesis of the research, the various research procedures utilized and the risks and benefits which were presented by such research procedures to the human research subjects exposed thereto;

2. the number of subjects which were involved in each human research protocol;

3. an itemization of the number of subjects involved in each human research protocol by race, ethnicity, age, sex, capacity to consent and mental disorder and a statement of how such consent was obtained when such mental disorder is extant which shall be supported by a copy of the relevant consent form;

4. a statement as to whether the human research review committee consider such human research to be non-therapeutic or possibly therapeutic;

5. a statement as to whether the human research review committee considered such human research to present minimal risk or greater than minimal risk;

6. a description of the type of diseases, illnesses, symptoms and conditions which were studied in each such research protocol; and

7. a report of any unusual incidents or negative impacts, if any, suffered by the human subjects as a result of such research.

Failure to file this information on the required date, shall result in the immediate discontinuance of all human research for which such information was not provided, in a manner that safeguards the well being of the subjects. Furthermore, the commissioner shall halt further consideration of any new requests pending before him or her until such time as the research entity is in compliance.

All such data collected shall be made available to the public upon reasonable request.

§ 2449. Determination of capacity to provide informed consent to greater than minimal risk human research. No person shall be presumed to lack capacity to provide voluntary informed consent to human research solely because of the presence of a mental disorder that may affect decision making capacity. However, for any subject who has a mental disorder which may affect decision making capacity and for any subject who possesses questionable decision making capacity, a finding must be made as to whether such subject has the capacity to provide voluntary informed consent, and, if not, whether such subject has the capacity to assent.

Such a determination of capacity is a condition which must be met and made by a board certified psychiatrist who is independent of the human research entity and not employed by the institution conducting, sponsoring or housing such research, prior to the subject participating in any human research.

§ 2450. Permissible human research on children and persons who lack capacity to provide voluntary informed consent. 1. No greater than minimal risk, non-therapeutic human research shall be conducted on a child. However, a child may participate in possibly therapeutic, minimal risk and possible therapeutic, greater than minimal risk human research if the parent or legal guardian has provided voluntary informed consent.

2. Except as otherwise provided in this section, no greater than minimal risk, non-therapeutic human research shall be conducted on adults who lack capacity to provide voluntary informed consent to such human research.

3. An adult who lacks capacity to provide voluntary informed consent may become a subject of greater than minimal risk, non-therapeutic research provided that: (a) such adult provided such voluntary informed consent prior to such incapacity having developed by designating a research agent and executing a research advance directive; (b) the research is expected to yield generalizable knowledge important to the understanding or amelioration of the subject's disorder or condition; (c) the knowledge cannot be obtained without his or her participation; and (d) the subject assents, unless the individual has been determined to lack capacity to assent.

4. No possible therapeutic, greater than minimal risk human research shall be conducted on an adult who lacks capacity to provide voluntary informed consent to human research: (a) without the voluntary informed consent of the guardian or committee of the subject who is authorized to (i) consent to possibly therapeutic research; (ii) monitor such research and (iii) withdraw the consent and remove the subject from continued participation in the research if it is determined that such further participation is not in the subject's interest; or (b) without a court order upon a finding by such court that the subject lacks the capacity to provide voluntary informed consent and that participation by the subject in such human research is determined to be in the subject's best interest.

In making a determination of the subject's best interest, the following criteria shall be considered: (i) the risks and potential benefits of the human research; (ii) the medical and scientific alternatives available to the subject, including the choice not to treat the condition; and (iii) whether the human research protocol is consistent with what is then known about the wishes, beliefs and mores of the subject.

5. Regardless of capacity to consent, no adult shall be a subject of human research if he or she, at any time, objects to active or passive participation in such research.

6. Regardless of capacity to consent, no adult shall be a subject of human research without being first notified that he or she is to be a subject of human research and without being further notified that he or she has the absolute and unequivocal right to refuse to participate in such human research.

§ 2451. Monitoring human research. 1. For all greater than minimal risk research on individuals with a mental disorder that affects decision making capacity, the human research review committee must designate a medically responsible clinician to evaluate whether each subject's participation in research is appropriate.

2. The medically responsible clinician must be a licensed medical doctor skilled and knowledgeable about caring for persons with the conditions or diseases presented by the specific study population and must be independent of the research entity, except as specified in this subdivision.

For possible therapeutic research, the medically responsible clinician may be the subject's attending physician or a member of the subject's treatment team.

3. The duties of the medically responsible clinician include: (a) confirming that the level of risk (minimal risk or greater than minimal risk) and the type of research (possibly therapeutic or non-therapeutic) of the proposed research is unambiguously authorized by the research advance directive, if one exists; (b) ensuring that the research agent understands the goals and risks of the research, if a research agent has been designated; (c) ensuring that the subject assents to research participation, unless the subject has been determined to lack capacity to assent; (d) monitoring the subject for possible objection to continued participation; and (e) monitoring the subject to ensure that continued research participation would not be detrimental to the subject's well-being, considering all relevant circumstances.

§ 2452. Research agent and research advance directive. 1. Every adult shall be presumed capable of appointing a research agent unless such person has been adjudged by a court to be incapable of making health care decisions or adjudged by a court to be incapable of appointing a research agent, or unless a guardian has been appointed to make health care decisions for the adult pursuant to article eighty-one of the mental hygiene law or has been appointed pursuant to article seventeen-A of the surrogate's court procedure act.

(a) A research agent is designated by executing a research advance directive which is signed and dated by the adult in the presence of two adult witnesses who shall also sign the research advance directive.

(b) The witnesses shall state in writing:

(i) that the individual appeared to execute the research advance directive willingly and free from duress;

(ii) that the individual appeared to understand the differences among medical treatment, possibly therapeutic research and non-therapeutic research;

(iii) that the individual appeared to be able to express a choice about delegating authority for specific research participation decisions to the named research agent, understanding that such authority may be revoked at any time, may be limited to specific risk-benefit categories of research and would not prevent the individual from objecting to participate in the research; and

(iv) that the individual appeared to understand that he or she may ask a court to designate a guardian to make a determination as to the individual's participation in a particular research study.

2. For persons who reside in a mental hygiene facility operated or licensed by the New York state office of mental health, no witnesses shall be affiliated with the facility and, if the mental hygiene facility is also a hospital as defined in subdivision ten of section 1.03 of the mental hygiene law, at least one witness shall be a qualified psychiatrist.

3. For persons who reside in a mental hygiene facility operated or licensed by the New York state office of mental retardation and developmental disabilities, no witnesses shall be affiliated with the facility, and at least one witness shall be a physician or clinical psychologist who either is employed by a school named in section 13.17 of the mental hygiene law or who has been employed for a minimum of two years to render care and service in a facility operated or licensed by the office of mental retardation and developmental disabilities, or who has been approved by the commissioner of mental retardation and developmental disabilities in accordance with regulations approved by the commissioner which shall require that a physician or clinical psychologist possess specialized training or three years experience in treating developmental disabilities.

4. An operator, administrator, or employee of a hospital, mental hygiene facility, or psychiatric unit of a general hospital may not be appointed as a research agent by any person who, at the time of the appointment, is a patient or resident of, or has applied for admission to, such hospital, mental hygiene facility, or psychiatric unit of a general hospital, unless they are related to the principal by blood, marriage or adoption.

5. The research agent's authority shall commence upon a determination that the individual lacks capacity to make research participation decisions.

6. Research advance directives executed by persons determined to lack capacity to provide voluntary informed consent to research but, meeting the requirements in paragraph (b) of subdivision one of this section shall be limited to authorizing possibly therapeutic research and non-therapeutic research which does not pose more than minimal risk.

7. The research advance directive shall:

(a) identify the principal and the agent;

(b) indicate that the principal intends the agent to have authority to make research participation decisions on the principal's behalf;

(c) specify the principal's instructions about participation in specific risk-benefit categories or specific research; and

(d) include a statement that research is different from clinical care in that research is designed to gain new information that will help other persons in the future and not necessarily the participant in the research and that, for some research, there may be no expected medical benefit for the subject.

8. After consultation with interested persons, the commissioner shall prepare and distribute a model form of a research advance directive, the use of which shall be optional.

§ 6. This act shall take effect on the one hundred twentieth day after it shall have become a law; provided that the commissioner of health is authorized to promulgate any and all rules and regulations and take any other measures necessary to implement this act on its effective date on or before such effective date.