SENATE, No. 1757

STATE OF NEW JERSEY
212th LEGISLATURE

INTRODUCED MARCH 21, 2006

Sponsored by:
Senator JOSEPH F. VITALE
District 19 (Middlesex)

SYNOPSIS
"Access to Medical Research Act;" authorizes certain persons to give informed consent for medical research if subject of research is unable to give consent.

CURRENT VERSION OF TEXT
As introduced.
AN ACT concerning informed consent for medical research and
supplementing Title 26 of the Revised Statutes.

BE IT ENACTED by the Senate and General Assembly of the State
of New Jersey:

1. This act shall be known and may be cited as the "Access to
Medical Research Act."

2. The Legislature finds and declares that:
   a. Access to the latest treatments developed through medical
      research is essential to provide the citizens of this State with the
      best health care services available;
   b. The advancement of the scientific understanding of health, 
      behavior, disease, and treatment is a vital endeavor for the benefit
      of humankind;
   c. Ground-breaking research is currently being conducted in
      New Jersey by a wide variety of health professionals in the
      diagnosis, intervention and monitoring of all aspects of health and
      medical care; and
   d. All research involving human participants, regardless of the
      setting, must be conducted with profound respect for their health, 
      safety, and dignity.

3. The provisions of this act shall apply to medical research that:
   is approved and monitored by an institutional review board that 
   holds an assurance with the United States Department of Health and 
   Human Services; and relates to the cognitive impairment, lack of 
   capacity, or serious physical or behavioral conditions and life-
   threatening diseases of research participants.

4. As used in this act, "informed consent" means the
   authorization given pursuant to this act to participate in medical
   research performed on a subject after each of the following 
   conditions have been satisfied:
   a. The subject or his guardian, or authorized representative as 
      provided in section 5 of this act, as applicable, is informed both 
      verbally and within the written consent form, in nontechnical terms 
      and in a language in which the subject or the subject's guardian or 
      authorized representative is fluent, of the following facts of the 
      proposed medical research, which might influence the decision to
      participate in the research, including, but not limited to:
         (1) an explanation of the procedures to be followed in the
             research and any drugs or devices to be utilized, including the 
             purposes of the procedures, drugs, or devices;
         (2) a description of any attendant discomfort and risks to the 
             subject to be reasonably expected;
         (3) an explanation of any benefits to the subject to be reasonably
expected, if applicable;
   (4) a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits;
   (5) an estimate of the expected duration of the research procedure or study;
   (6) an offer to answer any inquiries concerning the research or the procedures involved;
   (7) an instruction to the subject or his guardian or authorized representative, as applicable, that he is free to withdraw his prior consent to the medical experiment and discontinue participation in the research at any time, without prejudice to the subject;
   (8) the name, institutional affiliation, if any, and address of the person or persons actually performing and primarily responsible for the conduct of the research;
   (9) the name of the sponsor or funding source, if any, or manufacturer if the research involves a drug or device, and the organization, if any, under whose general aegis the research is being conducted;
   (10) the name, address, and phone number of an impartial third party, not associated with the research, to whom the subject may address complaints about the research; and
   (11) the material financial stake or interest, if any, that the investigator or research institution has in the outcome of the research. For purposes of this section, "material" means $10,000 or more in securities or other assets valued at the date of disclosure, or in relevant cumulative salary or other income, regardless of when it is earned or expected to be earned or as otherwise determined by the research institution.

b. The subject or his guardian or authorized representative, as applicable, has signed and dated a written consent form.
   c. The written consent form is signed and dated by any person other than the subject or his guardian or authorized representative who can attest that the requirements for informed consent to the medical research have been satisfied.
   d. Consent is given voluntarily and freely by the subject or his guardian or authorized representative without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence.

5. a. For purposes of obtaining informed consent required for medical research in a non-emergency room environment, if a person who may be the subject of the research is unable to consent and does not express dissent or resistance to participation, surrogate informed consent may be obtained from an authorized representative with reasonable knowledge of the subject, who shall include any of the following persons, in the following descending order of priority:
(1) the health care representative of the subject pursuant to an advance directive for health care;
(2) the guardian of the subject who has the authority to make health care decisions for the subject;
(3) the spouse of the subject;
(4) the domestic partner, as defined in section 3 of P.L.2003, c.246 (C.26:8A-3), of the subject;
(5) an adult son or daughter of the subject;
(6) a custodial parent of the subject;
(7) an adult brother or sister of the subject;
(8) an adult grandchild of the subject;
(9) an available adult relative with the closest degree of kinship to the subject.

b. For purposes of obtaining informed consent required for medical research in an emergency room environment, if a person who may be the subject of the research is unable to consent and does not express dissent or resistance to participation, surrogate informed consent may be obtained from an authorized representative who is any of the following persons, in the following descending order of priority:
(1) the health care representative of the subject pursuant to an advance directive for health care;
(2) the guardian of the subject who has the authority to make health care decisions for the subject;
(3) the spouse of the subject;
(4) the domestic partner, as defined in section 3 of P.L.2003, c.246 (C.26:8A-3), of the subject;
(5) an adult son or daughter of the subject;
(6) a custodial parent of the subject;
(7) an adult brother or sister of the subject.

c. For the purposes of subsections a. and b. of this section:
(1) when there are two or more available persons who may give surrogate informed consent and who are in the same order of priority, if any of those persons expresses dissent as to the participation of the person in the research, consent shall not be considered as having been given; and
(2) when there are two or more available persons who are in different orders of priority, refusal to consent by a person who is a higher priority authorized representative shall not be superseded by the consent of a person who is a lower priority authorized representative.

d. An authorized representative described in this section shall exercise substituted judgment, and base decisions about participation in accordance with the subject's individual health care instructions, if any, and other wishes, to the extent known to the authorized representative. If the authorized representative does not have knowledge of any health care instructions or other wishes of the subject, he shall make the decision in accordance with the
subject's best interests. In determining the subject's best interests, the authorized representative shall consider the subject's personal values and his best estimation of what the subject would have chosen if he were capable of making a decision.

e. The requirement for obtaining informed consent for medical research pursuant to this act shall not apply to any medical research that benefits a person who is subject to a life-threatening emergency in accordance with the conditions set forth in 21 C.F.R.s.50.24.

f. The requirements for obtaining informed consent for medical research pursuant to this act may be altered or waived in accordance with the conditions set forth in 45 C.F.R.s.46.116(d).

g. A person who provides surrogate consent pursuant to this section may not receive financial compensation for providing the consent.

h. Except as otherwise provided by law, the provisions of this section shall not apply to an adult in a terminal condition who executes an advance directive for health care directing the withholding or withdrawal of life-sustaining procedures pursuant to P.L.1991, c.201 (C.26:2H-53 et seq.).

6. This act shall take effect immediately.

STATEMENT

This bill, the "Access to Medical Research Act," would authorize certain persons to give surrogate informed consent for a person to be subjected to medical research, if that person is not able to give that consent. The provisions of the bill would only apply to medical research that is approved and monitored by an institutional review board that holds an assurance with the United States Department of Health and Human Services and relates to the cognitive impairment, lack of capacity, or serious physical or behavioral conditions and life-threatening diseases of research participants.

The bill provides that:

- For purposes of obtaining informed consent required for medical research in a non-emergency room environment, if a person who may be the subject of the research is unable to consent and does not express dissent or resistance to participation, surrogate informed consent may be obtained from an authorized representative with reasonable knowledge of the subject, who shall include any of the following persons, in the following descending order of priority:
  1. the health care representative of the subject pursuant to an advance directive for health care;
  2. the guardian of the subject who has the authority to make health care decisions for the subject;
(3) the spouse of the subject;
(4) the domestic partner, as defined in section 3 of P.L.2003, c.246 (C.26:8A-3), of the subject;
(6) a custodial parent of the subject;
(7) any adult brother or sister of the subject;
(8) any adult grandchild of the subject;
(9) an available adult relative with the closest degree of kinship to the subject.

For purposes of obtaining informed consent required for medical research in an emergency room environment, if a person who may be the subject of the research is unable to consent and does not express dissent or resistance to participation, surrogate informed consent may be obtained from an authorized representative who is any of the following persons, in the following descending order of priority:

(1) the health care representative of the subject pursuant to an advance directive for health care;
(2) the guardian of the subject who has the authority to make health care decisions for the subject;
(3) the spouse of the subject;
(4) the domestic partner, as defined in section 3 of P.L.2003, c.246 (C.26:8A-3), of the subject;
(5) an adult son or daughter of the subject;
(6) a custodial parent of the subject;
(7) any adult brother or sister of the subject.

When there are two or more available persons who may give surrogate informed consent and who are in the same order of priority, if any of those persons expresses dissent as to the participation of the person in the research, consent shall not be considered as having been given.

When there are two or more available persons who are in different orders of priority, refusal to consent by a person who is a higher priority authorized representative shall not be superseded by the consent of a person who is a lower priority authorized representative.

An authorized representative shall exercise substituted judgment, and base decisions about participation in accordance with the subject's individual health care instructions, if any, and other wishes, to the extent known to the representative. If the representative does not have knowledge of any health care instructions or other wishes of the subject, he shall make the decision in accordance with the subject's best interests. In determining the subject's best interests, the representative shall consider the subject's personal values and his best estimation of what the subject would have chosen if he were capable of making a decision.

The requirement for obtaining informed consent shall not apply to any medical research that benefits a person who is subject to a
life-threatening emergency in accordance with the conditions set forth in 21C.F.R.s.50.24.

- The requirements for obtaining informed consent may be altered or waived in accordance with the conditions set forth in 45 C.F.R.s.46.116(d).

- A person who provides surrogate consent pursuant to this bill may not receive financial compensation for providing the consent.

- Except as otherwise provided by law, the provisions of this bill shall not apply to an adult in a terminal condition who executes an advance directive for health care directing the withholding or withdrawal of life-sustaining procedures pursuant to P.L.1991, c.201 (C.26:2H-53 et seq.).

- The bill defines “informed consent” to mean: the authorization given pursuant to this bill to participate in medical research performed on a subject after each of the conditions specified in the bill have been satisfied.