26:14-1

LEGISLATIVE HISTORY CHECKLIST

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LAWS OF: 2007 **CHAPTER:** 316

NJSA: 26:14-1 ("Access to Medical Research Act;" authorizes certain persons to give informed consent for medical research if subject of research is unable to give consent)

BILL NO: A2379 (Substituted for S1757)

SPONSOR(S) Caraballo and Others

DATE INTRODUCED: February 6, 2006

COMMITTEE: **ASSEMBLY:** Health and Senior Services

SENATE: Health, Human Services and Senior Citizens

AMENDED DURING PASSAGE: Yes

DATE OF PASSAGE: **ASSEMBLY:** January 7, 2008

SENATE: January 3, 2008

DATE OF APPROVAL: January 13, 2008

FOLLOWING ARE ATTACHED IF AVAILABLE:

FINAL TEXT OF BILL (Third reprint enacted)

A2379

SPONSOR'S STATEMENT: (Begins on page 5 of original bill) Yes

COMMITTEE STATEMENT: **ASSEMBLY**: Yes

SENATE: Yes

(Audio archived recordings of the committee meetings, corresponding to the date of the committee statement, may ***possibly*** be found at www.njleg.state.nj.us)

FLOOR AMENDMENT STATEMENT: Yes 12-10-07
12-17-07

LEGISLATIVE FISCAL NOTE: No

S1757

SPONSOR'S STATEMENT: (Begins on page 5 of original bill) Yes

COMMITTEE STATEMENT: **ASSEMBLY**: No

SENATE: Yes

FLOOR AMENDMENT STATEMENT: Yes

LEGISLATIVE FISCAL ESTIMATE: No

VETO MESSAGE: No

GOVERNOR'S PRESS RELEASE ON SIGNING: No

FOLLOWING WERE PRINTED:

To check for circulating copies, contact New Jersey State Government Publications at the State Library (609) 278-2640 ext. 103 or mailto:refdesk@njstatelib.org.

REPORTS: No

HEARINGS: No

NEWSPAPER ARTICLES: No

RWH 6/5/08

Title 26.
Chapter 14. (New)
Access to Medical
Research
§§1-5 -
C.26:14-1 to
26:14-5

P.L. 2007, CHAPTER 316, ***approved January 13, 2008***
Assembly, No. 2379 ***(Third Reprint)***

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 medical research [3]on persons with cognitive impairments, lack of capacity, or serious physical or behavioral conditions and life-threatening diseases[3] that[2][:][2] is approved and monitored by an institutional review board that holds an assurance with the United States Department of Health and Human Services[2][; and relates to the cognitive impairment, lack of capacity, or serious physical or behavioral conditions and life-threatening diseases of research participants] and either:

a. offers the prospect of direct benefit to the individual subject, provided that the institutional review board has determined that the

EXPLANATION – Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted in the law.

Matter underlined thus is new matter.
Matter enclosed in superscript numerals has been adopted as follows:
[1]Senate SHH committee amendments adopted May 21, 2007.
[2]Senate floor amendments adopted December 10, 2007.
[3]Senate floor amendments adopted December 17, 2007.

risk is justified by the anticipated benefits to the subject and that the relation of the anticipated benefit to the risk is at least as favorable to the subject as that presented by available alternative approaches. If a currently recognized treatment exists, the subject or his guardian or authorized representative, as applicable, shall be presented with the choice of the recognized treatment and the research protocol; or

b. does not offer the prospect of direct benefit to the individual subject, provided that the institutional review board has determined that it: (1) is likely to yield generalizable knowledge about the subject's disorder or condition; (2) by its very nature cannot be conducted without the participation of decisionally incapacitated persons as subjects; and (3) involves no more than a minor increase over minimal risk.

For purposes of this section, "minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological exams or tests[2].

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 [2][of the proposed medical research, which might influence the decision to participate in the research, including, but not limited to]that include[2]:

(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]and, when applicable, the use of placebo controls and the process by which persons will be assigned to control groups[2];

(2) a description of any attendant discomfort and [2]reasonably foreseeable[2] risks to the subject [2][to be reasonably expected]][2];

(3) an explanation of any [2]potential direct[2] benefits to the subject [2][to be]. If no such direct benefits are[2] reasonably expected, [2][if applicable] that fact should be made clear[2];

(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 [2]and an explanation of whom to contact for answers to pertinent questions about the research and the research subject's rights, and whom to contact in the event of a research-related injury[2];

(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 [2]and the contact information for the institutional review board connected with the research[2]; and

(11) the material financial stake or interest, if any, that the investigator or research institution has in the [2][outcome of the][2] 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 [2][any] a[2] person [2][other than] , who is not[2] the subject [2][or],[2] his guardian or authorized representative, or the researcher, and[2] 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 [2][any element of][2] force, fraud, deceit, duress, coercion or undue influence.

5. a. For purposes of obtaining informed consent required for medical research [2][in a non-emergency room environment][2], 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) [2]**[**the health care representative of the subject pursuant to an advance directive for health care;

(2)**]**[2] the guardian of the subject who has the authority to make health care decisions for the subject;

[2](2) the health care representative of the subject pursuant to an advance directive for health care;[2]

(3) the spouse [1]or civil union partner, as applicable,[1] 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. [2]**[**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 [1]or civil union partner, as applicable,[1] 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.**]** For purposes of this section, inability to consent shall mean that a subject is unable to consent if he is unable to voluntarily reason, understand, and appreciate the nature and consequences of proposed health research interventions, including the subject's diagnosis and prognosis, the burdens, benefits, and risks of, and alternatives to, any such research, and to reach an informed decision.

All adults are presumed to have the ability to consent unless determined otherwise pursuant to this section or other provisions of State law.

A determination that a subject is unable to consent, as well as the extent of his incapacity and the likelihood that he will regain decision-making capacity, shall be made by an attending physician with no connection to the proposed research and shall be made to a

reasonable degree of medical certainty.

A determination of incapacity shall promptly be given to the subject and to at least one person at the highest level reasonably available on the list of surrogates contained in subsection a. of this section.

Notwithstanding a determination of incapacity made pursuant to this section, a subject's objection to a determination of incapacity or objection to the proposed research intervention shall be binding, unless a court of competent jurisdiction determines that the subject lacks decision-making capacity.[2]

c. For the purposes of [2][subsections a. and b. of][2] 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 [2][exercise substituted judgment, and base] make[2] 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, [2]or if the instructions or wishes do not clearly indicate what decision should be made,[2] he shall make the decision in accordance with the subject's [2][best interests. In determining the subject's best interests, the authorized representative shall consider the subject's][2] 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 [2][that benefits] with respect to[2] 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 [2][apply to an adult in a terminal condition who executes] override[2] an advance directive for health care [2][directing

the withholding or withdrawal of life-sustaining procedures**]** executed[2] pursuant to P.L.1991, c.201 (C.26:2H-53 et seq.).

6. This act shall take effect immediately.

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

ASSEMBLY, No. 2379

STATE OF NEW JERSEY

212th LEGISLATURE

INTRODUCED FEBRUARY 6, 2006

Sponsored by:
Assemblyman WILFREDO CARABALLO
District 29 (Essex and Union)
Assemblyman ERIC MUNOZ
District 21 (Essex, Morris, Somerset and Union)
Assemblyman HERB CONAWAY, JR.
District 7 (Burlington and Camden)

Co-Sponsored by:
Assemblymen Gordon, Chivukula and Conners

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.

(Sponsorship Updated As Of: 1/30/2007)

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.

ASSEMBLY HEALTH AND SENIOR SERVICES COMMITTEE

STATEMENT TO

ASSEMBLY, No. 2379

STATE OF NEW JERSEY

DATED: FEBRUARY 23, 2006

The Assembly Health and Senior Services Committee reports favorably Assembly Bill No. 2379.

This bill, which is designated as 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 N.J.S.A.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 N.J.S.A.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 advanced directive for health care directing the withholding or

withdraw 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.

SENATE HEALTH, HUMAN SERVICES AND SENIOR CITIZENS COMMITTEE

STATEMENT TO

ASSEMBLY, No. 2379

with committee amendments

STATE OF NEW JERSEY

DATED: MAY 21, 2007

The Senate Health, Human Services and Senior Citizens Committee reports favorably and with committee amendments Assembly Bill No. 2379.

As amended by committee, 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:

  -- the health care representative of the subject pursuant to an advance directive for health care;

  -- the guardian of the subject who has the authority to make health care decisions for the subject;

  -- the spouse or civil union partner, as applicable, of the subject;

  -- the domestic partner of the subject;

  -- an adult son or daughter of the subject;

  -- a custodial parent of the subject;

  -- any adult brother or sister of the subject;

  -- any adult grandchild of the subject;

  -- 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:
  -- the health care representative of the subject pursuant to an advance directive for health care;
  -- the guardian of the subject who has the authority to make health care decisions for the subject;
  -- the spouse or civil union partner, as applicable, of the subject;
  -- the domestic partner of the subject;
  -- an adult son or daughter of the subject;
  -- a custodial parent of the subject;
  -- 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.

The committee amended the bill to add references to civil union partners in the same order of priority as spouses of the subject of the research.

As amended, this bill is identical to Senate Bill No. 1757 (SCA) (Vitale), which the committee also reported favorably on this date.

STATEMENT TO

[First Reprint]
ASSEMBLY, No. 2379

with Senate Floor Amendments
(Proposed By Senator VITALE)

ADOPTED: DECEMBER 10, 2007

The amendments do the following:

SECTION 3

- specify that the medical research covered under this bill shall be required to:

-- offer the prospect of direct benefit to the subject, provided that the institutional review board (IRB) has determined that the risk is justified by the anticipated benefits to the subject and that the relation of the anticipated benefit to the risk is at least as favorable to the subject as that presented by available alternative approaches. If a currently recognized treatment exists, the subject or his guardian or authorized representative, as applicable, is to be presented with the choice of both the recognized treatment and the research protocol; or

-- if the research does not offer the prospect of direct benefit to the individual subject, the IRB must determine that it: (1) is likely to yield generalizable knowledge about the subject's disorder or condition; (2) by its very nature cannot be conducted without the participation of decisionally incapacitated persons as subjects; and (3) involves no more than a minor increase over minimal risk.

- define "minimal risk" to mean that "the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

SECTION 4

- add the following requirements to the informed consent provision:

-- an explanation, when applicable, as to the use of placebo controls and the process by which persons will be assigned to control groups, an explanation of the potential direct benefits to the subject, and the requirement that if no such benefits are reasonably expected, that fact be made clear;

-- contact information for answering pertinent questions about the research and the research subject's rights, and whom to contact in the event of a research-related injury, and contact information for the institutional review board connected with the research; and

-- the requirement that the consent form be signed and dated by a person who is not the subject, guardian, authorized representative or researcher.

SECTION 5

- delete language that distinguished between emergency and non-emergency settings for purposes of obtaining informed consent;
- change the order of priority of surrogates so that guardians have priority over health care representatives;
- define “inability to consent,” and clarify that all adults are presumed to have the ability to consent unless determined otherwise;
- provide that a determination of incapacity be made to a reasonably degree of certainty by an attending physician with no connection to the research and be promptly given to the subject and at least one surrogate, who is to be of the highest available priority;
- provide that a subject’s objection to an incapacity determination or to the research be binding, unless a court of competent jurisdiction determines that the subject lacks decision-making capacity;
- clarify that an authorized representative is to make decisions in accordance with the subject’s wishes, rather than “exercise substituted judgment,” and deletes language that would permit the authorized representative to try to determine what would be in the subject’s best interests; and
- clarify that an advance directive for health care cannot be overridden by a surrogate.

STATEMENT TO

[Second Reprint]

ASSEMBLY, No. 2379

with Senate Floor Amendments
(Proposed By Senator VITALE)

ADOPTED: DECEMBER 17, 2007

The amendments restore the scope of the original bill to research on persons with cognitive impairments, lack of capacity, or serious physical or behavioral conditions and life-threatening diseases.

These floor amendments make this bill identical to Senate Bill No. 1757(1R)(SA)(Vitale).

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.

(Sponsorship Updated As Of: 5/11/2007)

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.

SENATE HEALTH, HUMAN SERVICES AND SENIOR CITIZENS COMMITTEE

STATEMENT TO

SENATE, No. 1757

with committee amendments

STATE OF NEW JERSEY

DATED: MAY 21, 2007

The Senate Health, Human Services and Senior Citizens Committee reports favorably and with committee amendments Senate Bill No. 1757.

As amended by committee, 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:

  -- the health care representative of the subject pursuant to an advance directive for health care;

  -- the guardian of the subject who has the authority to make health care decisions for the subject;

  -- the spouse or civil union partner, as applicable, of the subject;

  -- the domestic partner of the subject;

  -- an adult son or daughter of the subject;

  -- a custodial parent of the subject;

  -- any adult brother or sister of the subject;

  -- any adult grandchild of the subject;

  -- 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:
  -- the health care representative of the subject pursuant to an advance directive for health care;
  -- the guardian of the subject who has the authority to make health care decisions for the subject;
  -- the spouse or civil union partner, as applicable, of the subject;
  -- the domestic partner of the subject;
  -- an adult son or daughter of the subject;
  -- a custodial parent of the subject;
  -- 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.

The committee amended the bill to add references to civil union partners in the same order of priority as spouses of the subject of the research.

As amended, this bill is identical to Assembly Bill No. 2379 SCA (Caraballo/Munoz/Conaway), which the committee also reported favorably on this date.

STATEMENT TO

[First Reprint]
SENATE, No. 1757

with Senate Floor Amendments
(Proposed By Senator VITALE)

ADOPTED: DECEMBER 17, 2007

The amendments do the following:

SECTION 3

- restore the scope of the original bill to research on persons with cognitive impairments, lack of capacity, or serious physical or behavioral conditions and life-threatening diseases;
- specify that the medical research covered under this bill shall be required to:

-- offer the prospect of direct benefit to the subject, provided that the institutional review board (IRB) has determined that the risk is justified by the anticipated benefits to the subject and that the relation of the anticipated benefit to the risk is at least as favorable to the subject as that presented by available alternative approaches. If a currently recognized treatment exists, the subject or his guardian or authorized representative, as applicable, is to be presented with the choice of both the recognized treatment and the research protocol; or

-- if the research does not offer the prospect of direct benefit to the individual subject, the IRB must determine that it: (1) is likely to yield generalizable knowledge about the subject's disorder or condition; (2) by its very nature cannot be conducted without the participation of decisionally incapacitated persons as subjects; and (3) involves no more than a minor increase over minimal risk.

- define “minimal risk” to mean that “the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

SECTION 4

- add the following requirements to the informed consent provision:

-- an explanation, when applicable, as to the use of placebo controls and the process by which persons will be assigned to control groups, an explanation of the potential direct benefits to the subject, and the requirement that if no such benefits are reasonably expected, that fact be made clear;

-- contact information for answering pertinent questions about the research and the research subject’s rights, and whom to contact in the event of a research-related injury, and contact information for the institutional review board connected with the research; and

-- the requirement that the consent form be signed and dated by a person who is not the subject, guardian, authorized representative or researcher.

SECTION 5

- delete language that distinguished between emergency and non-emergency settings for purposes of obtaining informed consent;
- change the order of priority of surrogates so that guardians have priority over health care representatives;
- define "inability to consent," and clarify that all adults are presumed to have the ability to consent unless determined otherwise;
- provide that a determination of incapacity be made to a reasonably degree of certainty by an attending physician with no connection to the research and be promptly given to the subject and at least one surrogate, who is to be of the highest available priority;
- provide that a subject's objection to an incapacity determination or to the research be binding, unless a court of competent jurisdiction determines that the subject lacks decision-making capacity;
- clarify that an authorized representative is to make decisions in accordance with the subject's wishes, rather than "exercise substituted judgment," and deletes language that would permit the authorized representative to try to determine what would be in the subject's best interests; and
- clarify that an advance directive for health care cannot be overridden by a surrogate.

These floor amendments make this bill identical to Assembly Bill No. 2379(2R)(SA)(Caraballo/Munoz/Conaway).