

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*)

1 **AN ACT** concerning informed consent for medical research and
2 supplementing Title 26 of the Revised Statutes.

3

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

6

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

9

10 2. The Legislature finds and declares that:

11 a. Access to the latest treatments developed through medical
12 research is essential to provide the citizens of this State with the
13 best health care services available;

14 b. The advancement of the scientific understanding of health,
15 behavior, disease, and treatment is a vital endeavor for the benefit
16 of humankind;

17 c. Ground-breaking research is currently being conducted in New
18 Jersey by a wide variety of health professionals in the diagnosis,
19 intervention and monitoring of all aspects of health and medical
20 care; and

21 d. All research involving human participants, regardless of the
22 setting, must be conducted with profound respect for their health,
23 safety, and dignity.

24

25 3. The provisions of this act shall apply to medical research
26 medical research ³on persons with cognitive impairments, lack of
27 capacity, or serious physical or behavioral conditions and life-
28 threatening diseases³ that²[:]² is approved and monitored by an
29 institutional review board that holds an assurance with the United
30 States Department of Health and Human Services²[:]; and relates to
31 the cognitive impairment, lack of capacity, or serious physical or
32 behavioral conditions and life-threatening diseases of research
33 participants] and either:

34 a. offers the prospect of direct benefit to the individual subject,
35 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:

¹Senate SHH committee amendments adopted May 21, 2007.

²Senate floor amendments adopted December 10, 2007.

³Senate floor amendments adopted December 17, 2007.

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

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

15 For purposes of this section, "minimal risk" means that the
16 probability and magnitude of harm or discomfort anticipated in the
17 research are not greater than those ordinarily encountered in daily
18 life or during the performance of routine physical or psychological
19 exams or tests².

20

21 4. As used in this act, "informed consent" means the
22 authorization given pursuant to this act to participate in medical
23 research performed on a subject after each of the following
24 conditions have been satisfied:

25 a. The subject or his guardian, or authorized representative as
26 provided in section 5 of this act, as applicable, is informed both
27 verbally and within the written consent form, in nontechnical terms
28 and in a language in which the subject or the subject's guardian or
29 authorized representative is fluent, of the following facts ²[of the
30 proposed medical research, which might influence the decision to
31 participate in the research, including, but not limited to]that
32 include²:

33 (1) an explanation of the procedures to be followed in the
34 research and any drugs or devices to be utilized, including the
35 purposes of the procedures, drugs, or devices²and, when applicable,
36 the use of placebo controls and the process by which persons will
37 be assigned to control groups²;

38 (2) a description of any attendant discomfort and ²reasonably
39 foreseeable² risks to the subject ²[to be reasonably expected]²;

40 (3) an explanation of any ²potential direct² benefits to the subject
41 ²[to be]. If no such direct benefits are² reasonably expected, ²[if
42 applicable] that fact should be made clear²;

43 (4) a disclosure of any appropriate alternative procedures, drugs
44 or devices that might be advantageous to the subject, and their
45 relative risks and benefits;

46 (5) an estimate of the expected duration of the research
47 procedure or study;

1 (6) an offer to answer any inquiries concerning the research or
2 the procedures involved ²and an explanation of whom to contact for
3 answers to pertinent questions about the research and the research
4 subject's rights, and whom to contact in the event of a research-
5 related injury²;

6 (7) an instruction to the subject or his guardian or authorized
7 representative, as applicable, that he is free to withdraw his prior
8 consent to the medical experiment and discontinue participation in
9 the research at any time, without prejudice to the subject;

10 (8) the name, institutional affiliation, if any, and address of the
11 person or persons actually performing and primarily responsible for
12 the conduct of the research;

13 (9) the name of the sponsor or funding source, if any, or
14 manufacturer if the research involves a drug or device, and the
15 organization, if any, under whose general aegis the research is being
16 conducted;

17 (10) the name, address, and phone number of an impartial third
18 party, not associated with the research, to whom the subject may
19 address complaints about the research ²and the contact information
20 for the institutional review board connected with the research²; and

21 (11) the material financial stake or interest, if any, that the
22 investigator or research institution has in the ²[outcome of the]²
23 research. For purposes of this section, "material" means \$10,000 or
24 more in securities or other assets valued at the date of disclosure, or
25 in relevant cumulative salary or other income, regardless of when it
26 is earned or expected to be earned or as otherwise determined by
27 the research institution.

28 b. The subject or his guardian or authorized representative, as
29 applicable, has signed and dated a written consent form.

30 c. The written consent form is signed and dated by ²[any] a²
31 person ²[other than] , who is not² the subject ²[or],² his guardian
32 or authorized representative, or the researcher, and² who can attest
33 that the requirements for informed consent to the medical research
34 have been satisfied.

35 d. Consent is given voluntarily and freely by the subject or his
36 guardian or authorized representative without the intervention of
37 ²[any element of]² force, fraud, deceit, duress, coercion or undue
38 influence.

39

40 5. a. For purposes of obtaining informed consent required for
41 medical research ²[in a non-emergency room environment]², if a
42 person who may be the subject of the research is unable to consent
43 and does not express dissent or resistance to participation, surrogate
44 informed consent may be obtained from an authorized
45 representative with reasonable knowledge of the subject, who shall
46 include any of the following persons, in the following descending
47 order of priority:

- 1 (1) ²the health care representative of the subject pursuant to an
2 advance directive for health care;
- 3 (2) ²the guardian of the subject who has the authority to make
4 health care decisions for the subject;
- 5 ²(2) the health care representative of the subject pursuant to an
6 advance directive for health care;²
- 7 (3) the spouse ¹or civil union partner, as applicable,¹ of the
8 subject;
- 9 (4) the domestic partner, as defined in section 3 of P.L.2003,
10 c.246 (C.26:8A-3), of the subject;
- 11 (5) an adult son or daughter of the subject;
- 12 (6) a custodial parent of the subject;
- 13 (7) an adult brother or sister of the subject;
- 14 (8) an adult grandchild of the subject;
- 15 (9) an available adult relative with the closest degree of kinship
16 to the subject.
- 17 b. ²For purposes of obtaining informed consent required for
18 medical research in an emergency room environment, if a person
19 who may be the subject of the research is unable to consent and
20 does not express dissent or resistance to participation, surrogate
21 informed consent may be obtained from an authorized
22 representative who is any of the following persons, in the following
23 descending order of priority:
- 24 (1) the health care representative of the subject pursuant to an
25 advance directive for health care;
- 26 (2) the guardian of the subject who has the authority to make
27 health care decisions for the subject;
- 28 (3) the spouse ¹or civil union partner, as applicable,¹ of the
29 subject;
- 30 (4) the domestic partner, as defined in section 3 of P.L.2003,
31 c.246 (C.26:8A-3), of the subject;
- 32 (5) an adult son or daughter of the subject;
- 33 (6) a custodial parent of the subject;
- 34 (7) an adult brother or sister of the subject. ²For purposes of this
35 section, inability to consent shall mean that a subject is unable to
36 consent if he is unable to voluntarily reason, understand, and
37 appreciate the nature and consequences of proposed health research
38 interventions, including the subject's diagnosis and prognosis, the
39 burdens, benefits, and risks of, and alternatives to, any such
40 research, and to reach an informed decision.
- 41 All adults are presumed to have the ability to consent unless
42 determined otherwise pursuant to this section or other provisions of
43 State law.
- 44 A determination that a subject is unable to consent, as well as the
45 extent of his incapacity and the likelihood that he will regain
46 decision-making capacity, shall be made by an attending physician
47 with no connection to the proposed research and shall be made to a

1 reasonable degree of medical certainty.

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

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

11 c. For the purposes of ²[subsections a. and b. of]² this section:

12 (1) when there are two or more available persons who may give
13 surrogate informed consent and who are in the same order of
14 priority, if any of those persons expresses dissent as to the
15 participation of the person in the research, consent shall not be
16 considered as having been given; and

17 (2) when there are two or more available persons who are in
18 different orders of priority, refusal to consent by a person who is a
19 higher priority authorized representative shall not be superseded by
20 the consent of a person who is a lower priority authorized
21 representative.

22 d. An authorized representative described in this section shall
23 ²[exercise substituted judgment, and base] make² decisions about
24 participation in accordance with the subject's individual health care
25 instructions, if any, and other wishes, to the extent known to the
26 authorized representative. If the authorized representative does not
27 have knowledge of any health care instructions or other wishes of
28 the subject, ²or if the instructions or wishes do not clearly indicate
29 what decision should be made,² he shall make the decision in
30 accordance with the subject's ²[best interests. In determining the
31 subject's best interests, the authorized representative shall consider
32 the subject's]² personal values and his best estimation of what the
33 subject would have chosen if he were capable of making a decision.

34 e. The requirement for obtaining informed consent for medical
35 research pursuant to this act shall not apply to any medical research
36 ²[that benefits] with respect to² a person who is subject to a life-
37 threatening emergency in accordance with the conditions set forth
38 in 21 C.F.R.s.50.24.

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

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

45 h. Except as otherwise provided by law, the provisions of this
46 section shall not ²[apply to an adult in a terminal condition who
47 executes] override² an advance directive for health care ²[directing

1 the withholding or withdrawal of life-sustaining procedures]
2 executed² pursuant to P.L.1991, c.201 (C.26:2H-53 et seq.).

3

4 6. This act shall take effect immediately.

5

6

7

8

9 "Access to Medical Research Act;" authorizes certain persons to
10 give informed consent for medical research if subject of research is
11 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 Connors

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)

1 AN ACT concerning informed consent for medical research and
2 supplementing Title 26 of the Revised Statutes.

3

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

6

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

9

10 2. The Legislature finds and declares that:

11 a. Access to the latest treatments developed through medical
12 research is essential to provide the citizens of this State with the
13 best health care services available;

14 b. The advancement of the scientific understanding of health,
15 behavior, disease, and treatment is a vital endeavor for the benefit
16 of humankind;

17 c. Ground-breaking research is currently being conducted in New
18 Jersey by a wide variety of health professionals in the diagnosis,
19 intervention and monitoring of all aspects of health and medical
20 care; and

21 d. All research involving human participants, regardless of the
22 setting, must be conducted with profound respect for their health,
23 safety, and dignity.

24

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

31

32 4. As used in this act, "informed consent" means the
33 authorization given pursuant to this act to participate in medical
34 research performed on a subject after each of the following
35 conditions have been satisfied:

36 a. The subject or his guardian, or authorized representative as
37 provided in section 5 of this act, as applicable, is informed both
38 verbally and within the written consent form, in nontechnical terms
39 and in a language in which the subject or the subject's guardian or
40 authorized representative is fluent, of the following facts of the
41 proposed medical research, which might influence the decision to
42 participate in the research, including, but not limited to:

43 (1) an explanation of the procedures to be followed in the
44 research and any drugs or devices to be utilized, including the
45 purposes of the procedures, drugs, or devices;

46 (2) a description of any attendant discomfort and risks to the
47 subject to be reasonably expected;

48 (3) an explanation of any benefits to the subject to be reasonably

- 1 expected, if applicable;
- 2 (4) a disclosure of any appropriate alternative procedures, drugs
3 or devices that might be advantageous to the subject, and their
4 relative risks and benefits;
- 5 (5) an estimate of the expected duration of the research
6 procedure or study;
- 7 (6) an offer to answer any inquiries concerning the research or
8 the procedures involved;
- 9 (7) an instruction to the subject or his guardian or authorized
10 representative, as applicable, that he is free to withdraw his prior
11 consent to the medical experiment and discontinue participation in
12 the research at any time, without prejudice to the subject;
- 13 (8) the name, institutional affiliation, if any, and address of the
14 person or persons actually performing and primarily responsible for
15 the conduct of the research;
- 16 (9) the name of the sponsor or funding source, if any, or
17 manufacturer if the research involves a drug or device, and the
18 organization, if any, under whose general aegis the research is being
19 conducted;
- 20 (10) the name, address, and phone number of an impartial third
21 party, not associated with the research, to whom the subject may
22 address complaints about the research; and
- 23 (11) the material financial stake or interest, if any, that the
24 investigator or research institution has in the outcome of the
25 research. For purposes of this section, "material" means \$10,000 or
26 more in securities or other assets valued at the date of disclosure, or
27 in relevant cumulative salary or other income, regardless of when it
28 is earned or expected to be earned or as otherwise determined by
29 the research institution.
- 30 b. The subject or his guardian or authorized representative, as
31 applicable, has signed and dated a written consent form.
- 32 c. The written consent form is signed and dated by any person
33 other than the subject or his guardian or authorized representative
34 who can attest that the requirements for informed consent to the
35 medical research have been satisfied.
- 36 d. Consent is given voluntarily and freely by the subject or his
37 guardian or authorized representative without the intervention of
38 any element of force, fraud, deceit, duress, coercion or undue
39 influence.
- 40
- 41 5. a. For purposes of obtaining informed consent required for
42 medical research in a non-emergency room environment, if a person
43 who may be the subject of the research is unable to consent and
44 does not express dissent or resistance to participation, surrogate
45 informed consent may be obtained from an authorized
46 representative with reasonable knowledge of the subject, who shall
47 include any of the following persons, in the following descending
48 order of priority:

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

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

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

31 c. For the purposes of subsections a. and b. of this section:

32 (1) when there are two or more available persons who may give
33 surrogate informed consent and who are in the same order of
34 priority, if any of those persons expresses dissent as to the
35 participation of the person in the research, consent shall not be
36 considered as having been given; and

37 (2) when there are two or more available persons who are in
38 different orders of priority, refusal to consent by a person who is a
39 higher priority authorized representative shall not be superseded by
40 the consent of a person who is a lower priority authorized
41 representative.

42 d. An authorized representative described in this section shall
43 exercise substituted judgment, and base decisions about
44 participation in accordance with the subject's individual health care
45 instructions, if any, and other wishes, to the extent known to the
46 authorized representative. If the authorized representative does not
47 have knowledge of any health care instructions or other wishes of
48 the subject, he shall make the decision in accordance with the

1 subject's best interests. In determining the subject's best interests,
2 the authorized representative shall consider the subject's personal
3 values and his best estimation of what the subject would have
4 chosen if he were capable of making a decision.

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

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

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

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

20

21 6. This act shall take effect immediately.

22

23

24

STATEMENT

25

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

36 The bill provides that:

- 37 • For purposes of obtaining informed consent required for medical
38 research in a non-emergency room environment, if a person who
39 may be the subject of the research is unable to consent and does
40 not express dissent or resistance to participation, surrogate
41 informed consent may be obtained from an authorized
42 representative with reasonable knowledge of the subject, who
43 shall include any of the following persons, in the following
44 descending order of priority:

45 (1) the health care representative of the subject pursuant to an
46 advance directive for health care;

47 (2) the guardian of the subject who has the authority to make
48 health care decisions for the subject;

- 1 (3) the spouse of the subject;
 - 2 (4) the domestic partner, as defined in section 3 of P.L.2003,
 - 3 c.246 (C.26:8A-3), of the subject;
 - 4 (6) a custodial parent of the subject;
 - 5 (7) any adult brother or sister of the subject;
 - 6 (8) any adult grandchild of the subject;
 - 7 (9) an available adult relative with the closest degree of kinship
 - 8 to the subject.
- 9 • For purposes of obtaining informed consent required for medical
 - 10 research in an emergency room environment, if a person who
 - 11 may be the subject of the research is unable to consent and does
 - 12 not express dissent or resistance to participation, surrogate
 - 13 informed consent may be obtained from an authorized
 - 14 representative who is any of the following persons, in the
 - 15 following descending order of priority:
 - 16 (1) the health care representative of the subject pursuant to an
 - 17 advance directive for health care;
 - 18 (2) the guardian of the subject who has the authority to make
 - 19 health care decisions for the subject;
 - 20 (3) the spouse of the subject;
 - 21 (4) the domestic partner, as defined in section 3 of P.L.2003,
 - 22 c.246 (C.26:8A-3), of the subject;
 - 23 (5) an adult son or daughter of the subject;
 - 24 (6) a custodial parent of the subject;
 - 25 (7) any adult brother or sister of the subject.
 - 26 • When there are two or more available persons who may give
 - 27 surrogate informed consent and who are in the same order of
 - 28 priority, if any of those persons expresses dissent as to the
 - 29 participation of the person in the research, consent shall not be
 - 30 considered as having been given.
 - 31 • When there are two or more available persons who are in
 - 32 different orders of priority, refusal to consent by a person who is
 - 33 a higher priority authorized representative shall not be
 - 34 superseded by the consent of a person who is a lower priority
 - 35 authorized representative.
 - 36 • An authorized representative shall exercise substituted judgment,
 - 37 and base decisions about participation in accordance with the
 - 38 subject's individual health care instructions, if any, and other
 - 39 wishes, to the extent known to the representative. If the
 - 40 representative does not have knowledge of any health care
 - 41 instructions or other wishes of the subject, he shall make the
 - 42 decision in accordance with the subject's best interests. In
 - 43 determining the subject's best interests, the representative shall
 - 44 consider the subject's personal values and his best estimation of
 - 45 what the subject would have chosen if he were capable of
 - 46 making a decision.
 - 47 • The requirement for obtaining informed consent shall not apply
 - 48 to any medical research that benefits a person who is subject to a

A2379 CARABALLO, MUNOZ

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- 1 life-threatening emergency in accordance with the conditions set
2 forth in 21C.F.R.s.50.24.
- 3 • The requirements for obtaining informed consent may be altered
4 or waived in accordance with the conditions set forth in 45
5 C.F.R.s.46.116(d).
 - 6 • A person who provides surrogate consent pursuant to this bill
7 may not receive financial compensation for providing the
8 consent.
 - 9 • Except as otherwise provided by law, the provisions of this bill
10 shall not apply to an adult in a terminal condition who executes
11 an advance directive for health care directing the withholding or
12 withdrawal of life-sustaining procedures pursuant to P.L.1991,
13 c.201 (C.26:2H-53 et seq.).
 - 14 • The bill defines "informed consent" to mean: the authorization
15 given pursuant to this bill to participate in medical research
16 performed on a subject after each of the conditions specified in
17 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)

S1757 VITALE

2

1 AN ACT concerning informed consent for medical research and
2 supplementing Title 26 of the Revised Statutes.

3

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

6

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

9

10 2. The Legislature finds and declares that:

11 a. Access to the latest treatments developed through medical
12 research is essential to provide the citizens of this State with the
13 best health care services available;

14 b. The advancement of the scientific understanding of health,
15 behavior, disease, and treatment is a vital endeavor for the benefit
16 of humankind;

17 c. Ground-breaking research is currently being conducted in
18 New Jersey by a wide variety of health professionals in the
19 diagnosis, intervention and monitoring of all aspects of health and
20 medical care; and

21 d. All research involving human participants, regardless of the
22 setting, must be conducted with profound respect for their health,
23 safety, and dignity.

24

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

31

32 4. As used in this act, "informed consent" means the
33 authorization given pursuant to this act to participate in medical
34 research performed on a subject after each of the following
35 conditions have been satisfied:

36 a. The subject or his guardian, or authorized representative as
37 provided in section 5 of this act, as applicable, is informed both
38 verbally and within the written consent form, in nontechnical terms
39 and in a language in which the subject or the subject's guardian or
40 authorized representative is fluent, of the following facts of the
41 proposed medical research, which might influence the decision to
42 participate in the research, including, but not limited to:

43 (1) an explanation of the procedures to be followed in the
44 research and any drugs or devices to be utilized, including the
45 purposes of the procedures, drugs, or devices;

46 (2) a description of any attendant discomfort and risks to the
47 subject to be reasonably expected;

48 (3) an explanation of any benefits to the subject to be reasonably

- 1 expected, if applicable;
- 2 (4) a disclosure of any appropriate alternative procedures, drugs
3 or devices that might be advantageous to the subject, and their
4 relative risks and benefits;
- 5 (5) an estimate of the expected duration of the research
6 procedure or study;
- 7 (6) an offer to answer any inquiries concerning the research or
8 the procedures involved;
- 9 (7) an instruction to the subject or his guardian or authorized
10 representative, as applicable, that he is free to withdraw his prior
11 consent to the medical experiment and discontinue participation in
12 the research at any time, without prejudice to the subject;
- 13 (8) the name, institutional affiliation, if any, and address of the
14 person or persons actually performing and primarily responsible for
15 the conduct of the research;
- 16 (9) the name of the sponsor or funding source, if any, or
17 manufacturer if the research involves a drug or device, and the
18 organization, if any, under whose general aegis the research is being
19 conducted;
- 20 (10) the name, address, and phone number of an impartial third
21 party, not associated with the research, to whom the subject may
22 address complaints about the research; and
- 23 (11) the material financial stake or interest, if any, that the
24 investigator or research institution has in the outcome of the
25 research. For purposes of this section, "material" means \$10,000 or
26 more in securities or other assets valued at the date of disclosure, or
27 in relevant cumulative salary or other income, regardless of when it
28 is earned or expected to be earned or as otherwise determined by
29 the research institution.
- 30 b. The subject or his guardian or authorized representative, as
31 applicable, has signed and dated a written consent form.
- 32 c. The written consent form is signed and dated by any person
33 other than the subject or his guardian or authorized representative
34 who can attest that the requirements for informed consent to the
35 medical research have been satisfied.
- 36 d. Consent is given voluntarily and freely by the subject or his
37 guardian or authorized representative without the intervention of
38 any element of force, fraud, deceit, duress, coercion or undue
39 influence.
- 40
- 41 5. a. For purposes of obtaining informed consent required for
42 medical research in a non-emergency room environment, if a person
43 who may be the subject of the research is unable to consent and
44 does not express dissent or resistance to participation, surrogate
45 informed consent may be obtained from an authorized
46 representative with reasonable knowledge of the subject, who shall
47 include any of the following persons, in the following descending
48 order of priority:

S1757 VITALE

- 1 (1) the health care representative of the subject pursuant to an
- 2 advance directive for health care;
- 3 (2) the guardian of the subject who has the authority to make
- 4 health care decisions for the subject;
- 5 (3) the spouse of the subject;
- 6 (4) the domestic partner, as defined in section 3 of P.L.2003,
- 7 c.246 (C.26:8A-3), of the subject;
- 8 (5) an adult son or daughter of the subject;
- 9 (6) a custodial parent of the subject;
- 10 (7) an adult brother or sister of the subject;
- 11 (8) an adult grandchild of the subject;
- 12 (9) an available adult relative with the closest degree of kinship
- 13 to the subject.
- 14 b. For purposes of obtaining informed consent required for
- 15 medical research in an emergency room environment, if a person
- 16 who may be the subject of the research is unable to consent and
- 17 does not express dissent or resistance to participation, surrogate
- 18 informed consent may be obtained from an authorized
- 19 representative who is any of the following persons, in the following
- 20 descending order of priority:
- 21 (1) the health care representative of the subject pursuant to an
- 22 advance directive for health care;
- 23 (2) the guardian of the subject who has the authority to make
- 24 health care decisions for the subject;
- 25 (3) the spouse of the subject;
- 26 (4) the domestic partner, as defined in section 3 of P.L.2003,
- 27 c.246 (C.26:8A-3), of the subject;
- 28 (5) an adult son or daughter of the subject;
- 29 (6) a custodial parent of the subject;
- 30 (7) an adult brother or sister of the subject.
- 31 c. For the purposes of subsections a. and b. of this section:
- 32 (1) when there are two or more available persons who may give
- 33 surrogate informed consent and who are in the same order of
- 34 priority, if any of those persons expresses dissent as to the
- 35 participation of the person in the research, consent shall not be
- 36 considered as having been given; and
- 37 (2) when there are two or more available persons who are in
- 38 different orders of priority, refusal to consent by a person who is a
- 39 higher priority authorized representative shall not be superseded by
- 40 the consent of a person who is a lower priority authorized
- 41 representative.
- 42 d. An authorized representative described in this section shall
- 43 exercise substituted judgment, and base decisions about
- 44 participation in accordance with the subject's individual health care
- 45 instructions, if any, and other wishes, to the extent known to the
- 46 authorized representative. If the authorized representative does not
- 47 have knowledge of any health care instructions or other wishes of
- 48 the subject, he shall make the decision in accordance with the

1 subject's best interests. In determining the subject's best interests,
2 the authorized representative shall consider the subject's personal
3 values and his best estimation of what the subject would have
4 chosen if he were capable of making a decision.

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

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

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

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

20

21 6. This act shall take effect immediately.

22

23

24

STATEMENT

25

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

36 The bill provides that:

- 37 • For purposes of obtaining informed consent required for medical
38 research in a non-emergency room environment, if a person who
39 may be the subject of the research is unable to consent and does
40 not express dissent or resistance to participation, surrogate
41 informed consent may be obtained from an authorized
42 representative with reasonable knowledge of the subject, who
43 shall include any of the following persons, in the following
44 descending order of priority:

45 (1) the health care representative of the subject pursuant to an
46 advance directive for health care;

47 (2) the guardian of the subject who has the authority to make
48 health care decisions for the subject;

S1757 VITALE

- 1 (3) the spouse of the subject;
 - 2 (4) the domestic partner, as defined in section 3 of P.L.2003,
 - 3 c.246 (C.26:8A-3), of the subject;
 - 4 (6) a custodial parent of the subject;
 - 5 (7) any adult brother or sister of the subject;
 - 6 (8) any adult grandchild of the subject;
 - 7 (9) an available adult relative with the closest degree of kinship
 - 8 to the subject.
- 9 • For purposes of obtaining informed consent required for medical
 - 10 research in an emergency room environment, if a person who
 - 11 may be the subject of the research is unable to consent and does
 - 12 not express dissent or resistance to participation, surrogate
 - 13 informed consent may be obtained from an authorized
 - 14 representative who is any of the following persons, in the
 - 15 following descending order of priority:
 - 16 (1) the health care representative of the subject pursuant to an
 - 17 advance directive for health care;
 - 18 (2) the guardian of the subject who has the authority to make
 - 19 health care decisions for the subject;
 - 20 (3) the spouse of the subject;
 - 21 (4) the domestic partner, as defined in section 3 of P.L.2003,
 - 22 c.246 (C.26:8A-3), of the subject;
 - 23 (5) an adult son or daughter of the subject;
 - 24 (6) a custodial parent of the subject;
 - 25 (7) any adult brother or sister of the subject.
 - 26 • When there are two or more available persons who may give
 - 27 surrogate informed consent and who are in the same order of
 - 28 priority, if any of those persons expresses dissent as to the
 - 29 participation of the person in the research, consent shall not be
 - 30 considered as having been given.
 - 31 • When there are two or more available persons who are in
 - 32 different orders of priority, refusal to consent by a person who is
 - 33 a higher priority authorized representative shall not be
 - 34 superseded by the consent of a person who is a lower priority
 - 35 authorized representative.
 - 36 • An authorized representative shall exercise substituted judgment,
 - 37 and base decisions about participation in accordance with the
 - 38 subject's individual health care instructions, if any, and other
 - 39 wishes, to the extent known to the representative. If the
 - 40 representative does not have knowledge of any health care
 - 41 instructions or other wishes of the subject, he shall make the
 - 42 decision in accordance with the subject's best interests. In
 - 43 determining the subject's best interests, the representative shall
 - 44 consider the subject's personal values and his best estimation of
 - 45 what the subject would have chosen if he were capable of
 - 46 making a decision.
 - 47 • The requirement for obtaining informed consent shall not apply
 - 48 to any medical research that benefits a person who is subject to a

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7

- 1 life-threatening emergency in accordance with the conditions set
2 forth in 21C.F.R.s.50.24.
- 3 • The requirements for obtaining informed consent may be altered
4 or waived in accordance with the conditions set forth in 45
5 C.F.R.s.46.116(d).
 - 6 • A person who provides surrogate consent pursuant to this bill
7 may not receive financial compensation for providing the
8 consent.
 - 9 • Except as otherwise provided by law, the provisions of this bill
10 shall not apply to an adult in a terminal condition who executes
11 an advance directive for health care directing the withholding or
12 withdrawal of life-sustaining procedures pursuant to P.L.1991,
13 c.201 (C.26:2H-53 et seq.).
 - 14 • The bill defines "informed consent" to mean: the authorization
15 given pursuant to this bill to participate in medical research
16 performed on a subject after each of the conditions specified in the
17 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).