

[Third Reprint]

**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:**

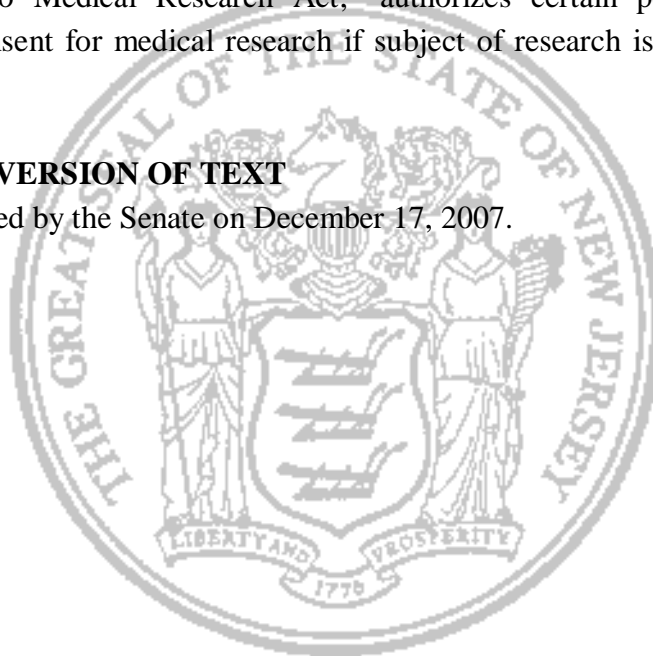
**Assemblymen Gordon, Chivukula, Connors and Senator Vitale**

**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 amended by the Senate on December 17, 2007.



**(Sponsorship Updated As Of: 1/4/2008)**

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 <sup>3</sup>on persons with cognitive impairments, lack of  
27 capacity, or serious physical or behavioral conditions and life-  
28 threatening diseases<sup>3</sup> that<sup>2</sup>[:]<sup>2</sup> is approved and monitored by an  
29 institutional review board that holds an assurance with the United  
30 States Department of Health and Human Services<sup>2</sup>[:]; 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  
36 risk is justified by the anticipated benefits to the subject and that the  
37 relation of the anticipated benefit to the risk is at least as favorable  
38 to the subject as that presented by available alternative approaches.  
39 If a currently recognized treatment exists, the subject or his  
40 guardian or authorized representative, as applicable, shall be  
41 presented with the choice of the recognized treatment and the  
42 research protocol; or

**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:**

<sup>1</sup>Senate SHH committee amendments adopted May 21, 2007.

<sup>2</sup>Senate floor amendments adopted December 10, 2007.

<sup>3</sup>Senate floor amendments adopted December 17, 2007.

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

8        For purposes of this section, "minimal risk" means that the  
9 probability and magnitude of harm or discomfort anticipated in the  
10 research are not greater than those ordinarily encountered in daily  
11 life or during the performance of routine physical or psychological  
12 exams or tests<sup>2</sup>.

13  
14        4. As used in this act, "informed consent" means the  
15 authorization given pursuant to this act to participate in medical  
16 research performed on a subject after each of the following  
17 conditions have been satisfied:

18        a. The subject or his guardian, or authorized representative as  
19 provided in section 5 of this act, as applicable, is informed both  
20 verbally and within the written consent form, in nontechnical terms  
21 and in a language in which the subject or the subject's guardian or  
22 authorized representative is fluent, of the following facts <sup>2</sup>[of the  
23 proposed medical research, which might influence the decision to  
24 participate in the research, including, but not limited to]that  
25 include<sup>2</sup>:

26        (1) an explanation of the procedures to be followed in the  
27 research and any drugs or devices to be utilized, including the  
28 purposes of the procedures, drugs, or devices<sup>2</sup>and, when applicable,  
29 the use of placebo controls and the process by which persons will  
30 be assigned to control groups<sup>2</sup>;

31        (2) a description of any attendant discomfort and <sup>2</sup>reasonably  
32 foreseeable<sup>2</sup> risks to the subject <sup>2</sup>[to be reasonably expected]<sup>2</sup>;

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

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

39        (5) an estimate of the expected duration of the research  
40 procedure or study;

41        (6) an offer to answer any inquiries concerning the research or  
42 the procedures involved <sup>2</sup>and an explanation of whom to contact for  
43 answers to pertinent questions about the research and the research  
44 subject's rights, and whom to contact in the event of a research-  
45 related injury<sup>2</sup>;

46        (7) an instruction to the subject or his guardian or authorized  
47 representative, as applicable, that he is free to withdraw his prior

1 consent to the medical experiment and discontinue participation in  
2 the research at any time, without prejudice to the subject;

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

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

10 (10) the name, address, and phone number of an impartial third  
11 party, not associated with the research, to whom the subject may  
12 address complaints about the research <sup>2</sup>and the contact information  
13 for the institutional review board connected with the research<sup>2</sup>; and

14 (11) the material financial stake or interest, if any, that the  
15 investigator or research institution has in the <sup>2</sup>[outcome of the]<sup>2</sup>  
16 research. For purposes of this section, “material” means \$10,000 or  
17 more in securities or other assets valued at the date of disclosure, or  
18 in relevant cumulative salary or other income, regardless of when it  
19 is earned or expected to be earned or as otherwise determined by  
20 the research institution.

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

23 c. The written consent form is signed and dated by <sup>2</sup>[any] a<sup>2</sup>  
24 person <sup>2</sup>[other than] , who is not<sup>2</sup> the subject <sup>2</sup>[or],<sup>2</sup> his guardian  
25 or authorized representative, or the researcher, and<sup>2</sup> who can attest  
26 that the requirements for informed consent to the medical research  
27 have been satisfied.

28 d. Consent is given voluntarily and freely by the subject or his  
29 guardian or authorized representative without the intervention of  
30 <sup>2</sup>[any element of]<sup>2</sup> force, fraud, deceit, duress, coercion or undue  
31 influence.

32

33 5. a. For purposes of obtaining informed consent required for  
34 medical research <sup>2</sup>[in a non-emergency room environment]<sup>2</sup>, if a  
35 person who may be the subject of the research is unable to consent  
36 and does not express dissent or resistance to participation, surrogate  
37 informed consent may be obtained from an authorized  
38 representative with reasonable knowledge of the subject, who shall  
39 include any of the following persons, in the following descending  
40 order of priority:

41 (1) <sup>2</sup>[the health care representative of the subject pursuant to an  
42 advance directive for health care;

43 (2)]<sup>2</sup> the guardian of the subject who has the authority to make  
44 health care decisions for the subject;

45 <sup>2</sup>(2) the health care representative of the subject pursuant to an  
46 advance directive for health care;<sup>2</sup>

47 (3) the spouse <sup>1</sup>or civil union partner, as applicable,<sup>1</sup> of the

1 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 (5) an adult son or daughter of the subject;

5 (6) a custodial parent of the subject;

6 (7) an adult brother or sister of the subject;

7 (8) an adult grandchild of the subject;

8 (9) an available adult relative with the closest degree of kinship  
9 to the subject.

10 b. <sup>2</sup>【For purposes of obtaining informed consent required for  
11 medical research in an emergency room environment, if a person  
12 who may be the subject of the research is unable to consent and  
13 does not express dissent or resistance to participation, surrogate  
14 informed consent may be obtained from an authorized  
15 representative who is any of the following persons, in the following  
16 descending order of priority:

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

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

21 (3) the spouse <sup>1</sup>or civil union partner, as applicable,<sup>1</sup> of the  
22 subject;

23 (4) the domestic partner, as defined in section 3 of P.L.2003,  
24 c.246 (C.26:8A-3), of the subject;

25 (5) an adult son or daughter of the subject;

26 (6) a custodial parent of the subject;

27 (7) an adult brother or sister of the subject.】 For purposes of this  
28 section, inability to consent shall mean that a subject is unable to  
29 consent if he is unable to voluntarily reason, understand, and  
30 appreciate the nature and consequences of proposed health research  
31 interventions, including the subject's diagnosis and prognosis, the  
32 burdens, benefits, and risks of, and alternatives to, any such  
33 research, and to reach an informed decision.

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

37 A determination that a subject is unable to consent, as well as the  
38 extent of his incapacity and the likelihood that he will regain  
39 decision-making capacity, shall be made by an attending physician  
40 with no connection to the proposed research and shall be made to a  
41 reasonable degree of medical certainty.

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

46 Notwithstanding a determination of incapacity made pursuant to  
47 this section, a subject's objection to a determination of incapacity or  
48 objection to the proposed research intervention shall be binding.

1 unless a court of competent jurisdiction determines that the subject  
2 lacks decision-making capacity.<sup>2</sup>

3 c. For the purposes of <sup>2</sup>[subsections a. and b. of]<sup>2</sup> this section:

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

9 (2) when there are two or more available persons who are in  
10 different orders of priority, refusal to consent by a person who is a  
11 higher priority authorized representative shall not be superseded by  
12 the consent of a person who is a lower priority authorized  
13 representative.

14 d. An authorized representative described in this section shall  
15 <sup>2</sup>[exercise substituted judgment, and base] make<sup>2</sup> decisions about  
16 participation in accordance with the subject's individual health care  
17 instructions, if any, and other wishes, to the extent known to the  
18 authorized representative. If the authorized representative does not  
19 have knowledge of any health care instructions or other wishes of  
20 the subject, <sup>2</sup>or if the instructions or wishes do not clearly indicate  
21 what decision should be made,<sup>2</sup> he shall make the decision in  
22 accordance with the subject's <sup>2</sup>[best interests. In determining the  
23 subject's best interests, the authorized representative shall consider  
24 the subject's]<sup>2</sup> personal values and his best estimation of what the  
25 subject would have chosen if he were capable of making a decision.

26 e. The requirement for obtaining informed consent for medical  
27 research pursuant to this act shall not apply to any medical research  
28 <sup>2</sup>[that benefits] with respect to<sup>2</sup> a person who is subject to a life-  
29 threatening emergency in accordance with the conditions set forth  
30 in 21 C.F.R.s.50.24.

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

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

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

42

43 6. This act shall take effect immediately.