

52:17B-88.10

LEGISLATIVE HISTORY CHECKLIST

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LAWS OF: 2005 **CHAPTER:** 227

NJSA: 52:17B-88.10 (Concerns research in sudden death in infancy and early childhood)

BILL NO: S1684 (Substituted for A3960)

SPONSOR(S): Codey and others

DATE INTRODUCED: June 10, 2004

COMMITTEE: **ASSEMBLY:** Health and Human Services

SENATE: Health, Human Services and Senior Citizens

AMENDED DURING PASSAGE: Yes

DATE OF PASSAGE: **ASSEMBLY:** June 20, 2005

SENATE: March 21, 2005

DATE OF APPROVAL: September 22, 2005

FOLLOWING ARE ATTACHED IF AVAILABLE:

[FINAL TEXT OF BILL](#) (1st reprint enacted)

S1684

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

COMMITTEE STATEMENT: [ASSEMBLY:](#) [Yes](#)

[SENATE:](#) [Yes](#)

[FLOOR AMENDMENT STATEMENT:](#) [Yes](#)

LEGISLATIVE FISCAL ESTIMATE: No

A3960

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

COMMITTEE STATEMENT: [ASSEMBLY:](#) [Yes](#)

SENATE: No

FLOOR AMENDMENT STATEMENT: No

LEGISLATIVE FISCAL ESTIMATE: No

VETO MESSAGE: No

GOVERNOR'S PRESS RELEASE ON SIGNING: No

FOLLOWING WERE PRINTED:

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No

IS 11/8/07

P.L. 2005, CHAPTER 227, *approved September 22, 2005*

Senate, No. 1684 (*First Reprint*)

1 **AN ACT** concerning research in sudden death in infancy and early
2 childhood and amending and supplementing P.L.2000, c.24.

3

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

6

7 1. Section 2 of P.L.2000, c.24 (C.52:17B-88.10) is amended to
8 read as follows:

9 2. a. The State Medical Examiner, in consultation with the
10 Commissioner of Health and Senior Services, shall develop
11 standardized protocols for autopsies performed in those cases in which
12 the suspected cause of death of a child under one year of age is sudden
13 infant death syndrome and in which the child is between one and three
14 years of age and the death is sudden and unexpected.

15 b. The State Medical Examiner shall establish a Sudden Child
16 Death Autopsy Protocol Committee to assist in developing and
17 reviewing the protocol. The committee shall include, but shall not be
18 limited to, the State Medical Examiner or his designee, the Assistant
19 Commissioner of the Division of Family Health Services in the
20 Department of Health and Senior Services or his designee, the
21 Director of the Division of Youth and Family Services in the
22 Department of Human Services or his designee, the director of the
23 SIDS Resource Center established pursuant to P.L.1987, c.331
24 (C.26:5D-4), an epidemiologist, a forensic pathologist, a pediatric
25 pathologist, a county medical examiner, a pediatrician who is
26 knowledgeable about sudden infant death syndrome and child abuse,
27 a law enforcement officer, an emergency medical technician or a
28 paramedic, a family member of a sudden infant death syndrome victim
29 and a family member of a sudden unexpected death victim who was
30 between one and three years of age at the time of death.

31 The committee shall annually review the protocol and make
32 recommendations to the State Medical Examiner to revise the
33 protocol, as appropriate.

34 c. The protocols shall include requirements and standards for scene
35 investigation, criteria for ascertaining the cause of death based on
36 autopsy, criteria for specific tissue sampling, and such other
37 requirements as the committee deems appropriate. The protocols shall
38 take into account nationally recognized standards for pediatric
39 autopsies.

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 floor amendments adopted February 14, 2005.

1 The State Medical Examiner shall be responsible for ensuring that
2 the protocols are followed by all medical examiners and other persons
3 authorized to conduct autopsies in those cases in which the suspected
4 cause of death is sudden infant death syndrome or in which the child
5 is between one and three years of age and the death is sudden and
6 unexpected.

7 d. The protocols shall authorize the [medical examiner] State
8 Medical Examiner¹, county medical examiner¹ or other authorized
9 person to [take] ¹[harvest] take¹ tissue samples for research
10 purposes [if the parent, parents or legal guardian of the deceased child
11 provides written consent for the taking of tissue samples for research
12 purposes], as provided in section 2 of P.L. , c. (C.)(pending before
13 the Legislature as this bill).

14 e. The sudden infant death syndrome autopsy protocol shall
15 provide that if the findings in the autopsy are consistent with the
16 definition of sudden infant death syndrome specified in the protocol,
17 the person who conducts the autopsy shall state on the death
18 certificate that sudden infant death syndrome is the cause of death.
19 (cf: P.L.2000, c.24, s.2)

20

21 2. (New section) The Legislature finds and declares that: advances
22 in genetics, biochemistry and other areas of medical research are
23 yielding new information about the specific causes of sudden death in
24 infancy and early childhood; these findings are of great importance
25 because the largest subgroup of these deaths, Sudden Infant Death
26 Syndrome, remains a "rule-out" diagnosis for which the family learns
27 what did not, rather than what did, cause the death of their child;
28 without knowing the actual cause, families are not able to determine
29 if there is a genetic basis that places their other children at risk, and
30 physicians are not able to prevent a death by prospectively diagnosing
31 and treating a potentially fatal medical problem; and if the State is to
32 meet its public health goal of reducing infant mortality, it is in the
33 public interest to accelerate efforts to identify actual causes of death
34 in infants and young children.

35 a. The State Medical Examiner, in consultation with the
36 Commissioner of Health and Senior Services and the Sudden Child
37 Death Autopsy Protocol Committee established pursuant to section 2
38 of P.L.2000, c.24 (C.52:17B-88.10) shall establish, pursuant to this
39 section, a protocol for participation by medical examiners in research
40 activities concerning deaths of children three years of age and younger.
41 The protocol shall be revised as necessary. The research shall include
42 all autopsies in which the suspected cause of death of a child under
43 one year of age is sudden infant death syndrome and the suspected
44 cause of death of a child three years of age and younger is not
45 considered a violent death pursuant to subsection a. of section 9 of
46 P.L.1967, c.234 (C.52:17B-86).

1 The protocol shall authorize the State Medical Examiner, county
2 medical examiner or other authorized person to ¹[harvest] take¹ and
3 transfer tissue samples to an approved research project prior to
4 obtaining the consent of the parent or legal guardian of the deceased
5 infant or young child, ¹[except that:]but¹ the research project shall
6 not be permitted to use the tissue prior to its obtaining consent as
7 provided in paragraph (3) of this subsection¹[; and no].

8 Notwithstanding the provisions of this section to the contrary, the
9 protocol shall provide that no¹ tissue sample shall be
10 ¹[harvested] taken¹ from a deceased infant or young child whose
11 parent or legal guardian has objected to an autopsy ¹because it is
12 contrary to the religious beliefs of the deceased,¹ in accordance with
13 section 2 of P.L.1983, c.535 (C.52:17B-88.2).

14 The protocol shall, at a minimum, stipulate that:

15 (1) the research project first be approved by the institutional
16 review board of the facility at which the research shall be conducted,
17 then by the Sudden Child Death Autopsy Protocol Committee, and
18 finally by the Institutional Review Board of the New Jersey
19 Department of Health and Senior Services. If a research project is
20 submitted by the Department of Health and Senior Services, the final
21 review of the project shall be conducted by an independent review
22 board;

23 (2) the research project delineate the information, other than the
24 tissue sample, that will be required from the investigation of the death
25 of the infant or young child;

26 (3) the research project develop a plan for the release by the State
27 Medical Examiner or county medical examiner, as applicable, of a
28 decedent's tissue, as well as obtaining written consent for the use of
29 the tissue and other identifying information from the parent or legal
30 guardian of the deceased infant or young child;

31 (4) the research project develop a plan for the disposal of a
32 decedent's tissue in the event that the parent or guardian does not give
33 consent for use of the tissue, and in cases in which consent is given,
34 upon completion of the research. The plan shall incorporate accepted
35 procedures for disposal of surgical biopsies and biohazardous
36 materials, and shall include procedures to inform the parent or
37 guardian and the Sudden Child Death Autopsy Protocol Committee of
38 the disposal plan;

39 (5) the research project reimburse the State Medical Examiner,
40 county medical examiner or other authorized person participating in
41 the research for reasonable costs incurred in ¹[harvesting] taking¹,
42 storing and providing tissue samples for the project. The estimated
43 costs subject to reimbursement shall be reviewed and approved by the
44 State Medical Examiner;

45 (6) the research project provide the State Medical Examiner and
46 the Sudden Child Death Autopsy Protocol Committee with periodic

1 updates on the status of the project; and

2 (7) the Sudden Child Death Autopsy Protocol Committee may
3 terminate a research project that is not in compliance with the research
4 project as approved pursuant to this subsection.

5 b. Upon receiving notification from the research project that the
6 research project has obtained written consent from the parent or legal
7 guardian of the deceased infant or young child for the use of tissue
8 samples and identifying information, the State Medical Examiner,
9 county medical examiner or other authorized person, as applicable,
10 shall provide the research project with copies of the autopsy reports
11 and any reports generated by the State Medical Examiner or county
12 medical examiner concerning the subject of the research.

13 c. The information and tissue samples provided by the State
14 Medical Examiner, county medical examiner or other authorized
15 person to the research project shall be used by the research project
16 only for the purposes approved by the Sudden Child Death Autopsy
17 Protocol Committee and as specified in the protocol, and shall not
18 otherwise be divulged or made public so as to disclose the identity of
19 any person to whom they relate. The information provided to the
20 research project shall not be considered a public record pursuant to
21 P.L.1963, c.73 (C.47:1A-1 et seq.) or P.L.2001, c.404 (C.47:1A-5 et
22 al.).

23 d. The Sudden Child Death Autopsy Protocol Committee shall
24 oversee the approved research projects.

25 e. The State Medical Examiner, county medical examiner, their
26 employees and other persons authorized by the State Medical
27 Examiner to provide tissue samples and identifying information to the
28 research project, and the members of the Sudden Child Death
29 Autopsy Protocol Committee shall not be liable for civil damages as
30 the result of any actions or omissions performed in good faith and in
31 accordance with the provisions of this act.

32

33 3. This act shall take effect on the 60th day after enactment.

34

35

36

37

38 _____
39 Authorizes State Medical Examiner to participate in research
concerning sudden death in infancy and early childhood.

SENATE, No. 1684

STATE OF NEW JERSEY
211th LEGISLATURE

INTRODUCED JUNE 10, 2004

Sponsored by:
Senator RICHARD J. CODEY
District 27 (Essex)

SYNOPSIS

Authorizes State Medical Examiner to participate in research concerning sudden death in infancy and early childhood.

CURRENT VERSION OF TEXT

As introduced.



S1684 CODEY

2

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13 infant death syndrome and in which the child is between one and three
14 years of age and the death is sudden and unexpected.

15 b. The State Medical Examiner shall establish a Sudden Child
16 Death Autopsy Protocol Committee to assist in developing and
17 reviewing the protocol. The committee shall include, but shall not be
18 limited to, the State Medical Examiner or his designee, the Assistant
19 Commissioner of the Division of Family Health Services in the
20 Department of Health and Senior Services or his designee, the
21 Director of the Division of Youth and Family Services in the
22 Department of Human Services or his designee, the director of the
23 SIDS Resource Center established pursuant to P.L.1987, c.331
24 (C.26:5D-4), an epidemiologist, a forensic pathologist, a pediatric
25 pathologist, a county medical examiner, a pediatrician who is
26 knowledgeable about sudden infant death syndrome and child abuse,
27 a law enforcement officer, an emergency medical technician or a
28 paramedic, a family member of a sudden infant death syndrome victim
29 and a family member of a sudden unexpected death victim who was
30 between one and three years of age at the time of death.

31 The committee shall annually review the protocol and make
32 recommendations to the State Medical Examiner to revise the
33 protocol, as appropriate.

34 c. The protocols shall include requirements and standards for scene
35 investigation, criteria for ascertaining the cause of death based on
36 autopsy, criteria for specific tissue sampling, and such other
37 requirements as the committee deems appropriate. The protocols shall
38 take into account nationally recognized standards for pediatric
39 autopsies.

40 The State Medical Examiner shall be responsible for ensuring that
41 the protocols are followed by all medical examiners and other persons
42 authorized to conduct autopsies in those cases in which the suspected
43 cause of death is sudden infant death syndrome or in which the child

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Matter underlined thus is new matter.

1 is between one and three years of age and the death is sudden and
2 unexpected.

3 d. The protocols shall authorize the [medical examiner] State
4 Medical Examiner or other authorized person to [take] harvest tissue
5 samples for research purposes [if the parent, parents or legal guardian
6 of the deceased child provides written consent for the taking of tissue
7 samples for research purposes], as provided in section 2 of P.L. , c.
8 (C.)(pending before the Legislature as this bill).

9 e. The sudden infant death syndrome autopsy protocol shall
10 provide that if the findings in the autopsy are consistent with the
11 definition of sudden infant death syndrome specified in the protocol,
12 the person who conducts the autopsy shall state on the death
13 certificate that sudden infant death syndrome is the cause of death.

14 (cf: P.L.2000, c.24, s.2)

15

16 2. (New section) The Legislature finds and declares that: advances
17 in genetics, biochemistry and other areas of medical research are
18 yielding new information about the specific causes of sudden death in
19 infancy and early childhood; these findings are of great importance
20 because the largest subgroup of these deaths, Sudden Infant Death
21 Syndrome, remains a "rule-out" diagnosis for which the family learns
22 what did not, rather than what did, cause the death of their child;
23 without knowing the actual cause, families are not able to determine
24 if there is a genetic basis that places their other children at risk, and
25 physicians are not able to prevent a death by prospectively diagnosing
26 and treating a potentially fatal medical problem; and if the State is to
27 meet its public health goal of reducing infant mortality, it is in the
28 public interest to accelerate efforts to identify actual causes of death
29 in infants and young children.

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42 The protocol shall authorize the State Medical Examiner, county
43 medical examiner or other authorized person to harvest and transfer
44 tissue samples to an approved research project prior to obtaining the
45 consent of the parent or legal guardian of the deceased infant or young
46 child, except that: the research project shall not be permitted to use

1 the tissue prior to its obtaining consent as provided in paragraph (3)
2 of this subsection; and no tissue sample shall be harvested from a
3 deceased infant or young child whose parent or legal guardian has
4 objected to an autopsy in accordance with section 2 of P.L.1983,
5 c.535 (C.52:17B-88.2).

6 The protocol shall, at a minimum, stipulate that:

7 (1) the research project first be approved by the institutional
8 review board of the facility at which the research shall be conducted,
9 then by the Sudden Child Death Autopsy Protocol Committee, and
10 finally by the Institutional Review Board of the New Jersey
11 Department of Health and Senior Services. If a research project is
12 submitted by the Department of Health and Senior Services, the final
13 review of the project shall be conducted by an independent review
14 board;

15 (2) the research project delineate the information, other than the
16 tissue sample, that will be required from the investigation of the death
17 of the infant or young child;

18 (3) the research project develop a plan for the release by the State
19 Medical Examiner or county medical examiner, as applicable, of a
20 decedent's tissue, as well as obtaining written consent for the use of
21 the tissue and other identifying information from the parent or legal
22 guardian of the deceased infant or young child;

23 (4) the research project develop a plan for the disposal of a
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25 consent for use of the tissue, and in cases in which consent is given,
26 upon completion of the research. The plan shall incorporate accepted
27 procedures for disposal of surgical biopsies and biohazardous
28 materials, and shall include procedures to inform the parent or
29 guardian and the Sudden Child Death Autopsy Protocol Committee of
30 the disposal plan;

31 (5) the research project reimburse the State Medical Examiner,
32 county medical examiner or other authorized person participating in
33 the research for reasonable costs incurred in harvesting, storing and
34 providing tissue samples for the project. The estimated costs subject
35 to reimbursement shall be reviewed and approved by the State Medical
36 Examiner;

37 (6) the research project provide the State Medical Examiner and
38 the Sudden Child Death Autopsy Protocol Committee with periodic
39 updates on the status of the project; and

40 (7) the Sudden Child Death Autopsy Protocol Committee may
41 terminate a research project that is not in compliance with the research
42 project as approved pursuant to this subsection.

43 b. Upon receiving notification from the research project that the
44 research project has obtained written consent from the parent or legal
45 guardian of the deceased infant or young child for the use of tissue
46 samples and identifying information, the State Medical Examiner,

1 county medical examiner or other authorized person, as applicable,
2 shall provide the research project with copies of the autopsy reports
3 and any reports generated by the State Medical Examiner or county
4 medical examiner concerning the subject of the research.

5 c. The information and tissue samples provided by the State
6 Medical Examiner, county medical examiner or other authorized
7 person to the research project shall be used by the research project
8 only for the purposes approved by the Sudden Child Death Autopsy
9 Protocol Committee and as specified in the protocol, and shall not
10 otherwise be divulged or made public so as to disclose the identity of
11 any person to whom they relate. The information provided to the
12 research project shall not be considered a public record pursuant to
13 P.L.1963, c.73 (C.47:1A-1 et seq.) or P.L.2001, c.404 (C.47:1A-5 et
14 al.).

15 d. The Sudden Child Death Autopsy Protocol Committee shall
16 oversee the approved research projects.

17 e. The State Medical Examiner, county medical examiner, their
18 employees and other persons authorized by the State Medical
19 Examiner to provide tissue samples and identifying information to the
20 research project, and the members of the Sudden Child Death
21 Autopsy Protocol Committee shall not be liable for civil damages as
22 the result of any actions or omissions performed in good faith and in
23 accordance with the provisions of this act.

24

25 3. This act shall take effect on the 60th day after enactment.

26

27

28

STATEMENT

29

30 Although advances in genetics, biochemistry and other areas of
31 medical research are yielding new information about the specific
32 causes of sudden death in infancy and early childhood, Sudden Infant
33 Death Syndrome (SIDS), remains a "rule-out" diagnosis for which the
34 family learns what did not, rather than what did, cause the death of
35 their child. Without knowing the actual cause of death, families are
36 not able to determine if there is a genetic basis that places their other
37 children at risk, and physicians are not able to prevent a death by
38 prospectively diagnosing and treating a potentially fatal medical
39 problem. To provide support to the families who lose children to
40 SIDS and sudden and unexpected death and to help children in the
41 future by determining the causes of these tragic deaths, this bill would
42 permit the State Medical Examiner to participate in research
43 concerning sudden and unexpected deaths of infants and young
44 children.

45 Specifically, the bill provides that:

46 -- The State Medical Examiner, in consultation with the Commissioner

1 of Health and Senior Services and the Sudden Child Death Autopsy
2 Protocol Committee established pursuant to N.J.S.A.52:17B-88.10,
3 shall establish a protocol for participation by medical examiners in
4 research activities concerning deaths of children three years of age and
5 younger. The research shall include all autopsies in which the
6 suspected cause of death of a child under one year of age is sudden
7 infant death syndrome and the suspected cause of death of a child
8 three years of age and younger is not considered to be an act of
9 violence. The bill includes all deaths of children under the age of three
10 to allow for more rigorous research that will include control groups.

11 The protocol shall authorize the State Medical Examiner, county
12 medical examiner or other authorized person to harvest and transfer
13 tissue samples to an approved research project prior to obtaining the
14 consent of the parent or legal guardian of the deceased infant or young
15 child, except that: the research project shall not be permitted to use
16 the tissue prior to obtaining consent of the parent or guardian; and no
17 tissue sample shall be harvested from a deceased infant or young child
18 whose parent or legal guardian has objected to an autopsy in
19 accordance with N.J.S.A.52:17B-88.2. The bill provides for the
20 harvesting and transfer of tissue samples to an approved research
21 project prior to obtaining the consent of the parent or legal guardian
22 in recognition of the fact that much of today's research requires unique
23 preservation and storing techniques of the tissue, which the medical
24 examiner will not have available. Therefore, since the research project
25 will have to assume responsibility for the preservation and storing of
26 the tissue, there is not sufficient time for the medical examiner or
27 researcher to obtain consent before the viable tissue must be
28 transferred. The bill is clear, however, that before the research project
29 can use the tissue, it must obtain the required consent.

30 The protocol shall, at a minimum, stipulate that:

31 - the research project first be approved by the institutional review
32 board of the facility at which the research shall be conducted, then by
33 the Sudden Child Death Autopsy Protocol Committee, and finally by
34 the Institutional Review Board of the New Jersey Department of
35 Health and Senior Services;

36 - the research project delineate the information, other than the
37 tissue sample, that will be required from the investigation of the death
38 of the infant or young child;

39 - the research project develop a plan for the release by the State
40 Medical Examiner or county medical examiner, as applicable, of a
41 decedent's tissue as well as obtaining written consent for the use of the
42 tissue and other identifying information from the parent or legal
43 guardian of the deceased infant or young child;

44 - the research project develop a plan for the disposal of a decedent's
45 tissue in the event that the parent or guardian does not give consent
46 for use of the tissue, and in cases in which consent is given, upon

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1 completion of the research. The plan shall incorporate accepted
2 procedures for disposal of surgical biopsies and biohazardous
3 materials, and shall include procedures to inform the parent or
4 guardian and the Sudden Child Death Autopsy Protocol Committee of
5 the disposal plan;

6 - the research project reimburse the State Medical Examiner, county
7 medical examiner or other authorized person participating in the
8 research for reasonable costs incurred in harvesting, storing and
9 providing tissue samples for the project. The estimated costs subject
10 to reimbursement shall be reviewed and approved by the State Medical
11 Examiner;

12 - the research project shall provide the State Medical Examiner and
13 the Sudden Child Death Autopsy Protocol Committee with periodic
14 updates on the status of the project; and

15 - the Sudden Child Death Autopsy Protocol Committee may
16 terminate a research project that is not in compliance with the research
17 project, as approved.

18 -- The State Medical Examiner, county medical examiner or other
19 authorized person, as applicable, shall provide the research project
20 with the tissue samples and copies of the autopsy reports and any
21 related reports generated by the State Medical Examiner or county
22 medical examiner concerning the subjects of the research (after the
23 research project has obtained the required written consent of the
24 parents or guardians).

25 -- The information and tissue samples provided by the State Medical
26 Examiner, county medical examiner or other authorized person to the
27 research project shall be used only by the research project for the
28 purposes approved by the Sudden Child Death Autopsy Protocol
29 Committee and as specified in the protocol, and shall not otherwise be
30 divulged or made public so as to disclose the identity of any person to
31 whom it relates.

32 -- The Sudden Child Death Autopsy Protocol Committee shall provide
33 oversight on the approved research projects.

34 -- The State Medical Examiner, county medical examiner, their
35 employees and other persons authorized by the State Medical
36 Examiner to provide tissue samples and identifying information to the
37 research project, and the members of the Sudden Child Death
38 Autopsy Protocol Committee shall not be liable for civil damages as
39 the result of any actions or omissions performed in good faith and in
40 accordance with the provisions of this bill.

ASSEMBLY HEALTH AND HUMAN SERVICES COMMITTEE

STATEMENT TO

[First Reprint]

SENATE, No. 1684

STATE OF NEW JERSEY

DATED: MAY 2, 2005

The Assembly Health and Human Services Committee reports favorably Senate Bill No. 1684 (1R).

This bill would permit the State Medical Examiner to participate in research concerning sudden and unexpected deaths of infants and young children.

The purpose of this bill is to provide support to the families who lose children to sudden infant death syndrome (SIDS) and sudden and unexpected death and to help children in the future by determining the causes of these tragic deaths.

The bill provides specifically as follows:

- C The State Medical Examiner, in consultation with the Commissioner of Health and Senior Services and the Sudden Child Death Autopsy Protocol Committee established pursuant to N.J.S.A.52:17B-88.10, is to establish a protocol for participation by medical examiners in research activities concerning deaths of children three years of age and younger. The research would include all autopsies in which the suspected cause of death of a child under one year of age is SIDS and the suspected cause of death of a child three years of age and younger is not considered to be an act of violence. The bill includes all deaths of children under the age of three to allow for more rigorous research that will include control groups.
- C The protocol is to authorize the State Medical Examiner, county medical examiner or other authorized person to take and transfer tissue samples to an approved research project prior to obtaining the consent of the parent or legal guardian of the deceased infant or young child, except that: the research project is not permitted to use the tissue prior to obtaining the consent of the parent or guardian; and no tissue sample is to be taken from a deceased infant or young child whose parent or legal guardian has objected to an autopsy in accordance with N.J.S.A.52:17B-88.2 because it is contrary to the religious beliefs of the deceased. (The bill provides for the taking and transfer of tissue samples to an approved research project prior to obtaining the consent of the parent or legal guardian in recognition of the fact that much of

today's research requires unique preservation and storing techniques of the tissue, which the medical examiner will not have available. Since the research project will have to assume responsibility for the preservation and storing of the tissue, there is not sufficient time for the medical examiner or researcher to obtain consent before the viable tissue must be transferred; however, the bill clearly requires that the research project obtain the required consent before it can use the tissue.)

C The protocol, at a minimum, is to stipulate that:

-- the research project first be approved by the institutional review board of the facility at which the research will be conducted, then by the Sudden Child Death Autopsy Protocol Committee, and finally by the Institutional Review Board of the New Jersey Department of Health and Senior Services;

-- the research project delineate the information, other than the tissue sample, that will be required from the investigation of the death of the infant or young child;

-- the research project develop a plan for the release by the State Medical Examiner or county medical examiner, as applicable, of a decedent's tissue, as well as obtaining written consent for the use of the tissue and other identifying information from the parent or legal guardian of the deceased infant or young child;

-- the research project develop a plan for the disposal of a decedent's tissue in the event that the parent or guardian does not give consent for use of the tissue, and in cases in which consent is given, upon completion of the research, which plan must incorporate accepted procedures for disposal of surgical biopsies and biohazardous materials, and include procedures to inform the parent or guardian and the Sudden Child Death Autopsy Protocol Committee of the disposal plan;

-- the research project reimburse the State Medical Examiner, county medical examiner or other authorized person participating in the research for reasonable costs incurred in taking, storing and providing tissue samples for the project, with the estimated costs subject to reimbursement to be reviewed and approved by the State Medical Examiner;

-- the research project provide the State Medical Examiner and the Sudden Child Death Autopsy Protocol Committee with periodic updates on the status of the project; and

-- the Sudden Child Death Autopsy Protocol Committee may terminate a research project that is not in compliance with the research project, as approved.

C The State Medical Examiner, county medical examiner or other authorized person, as applicable, is to provide the research project with the tissue samples and copies of the autopsy reports and any related reports generated by the State Medical Examiner or county medical examiner concerning the subjects of the research (after the research project has obtained the required written consent of the

parents or guardians). The information and tissue samples are to be used only by the research project for the purposes approved by the Sudden Child Death Autopsy Protocol Committee and as specified in the protocol, and are not otherwise to be divulged or made public so as to disclose the identity of any person to whom they relate. The Sudden Child Death Autopsy Protocol Committee is to oversee the approved research projects.

C Finally, the bill provides immunity from civil liability to the State Medical Examiner, county medical examiner, their employees and other persons authorized by the State Medical Examiner to provide tissue samples and identifying information to the research project, and to the members of the Sudden Child Death Autopsy Protocol Committee, for any actions or omissions performed in good faith and in accordance with the provisions of this bill.

C The bill takes effect on the 60th day after enactment.

This bill is identical to Assembly Bill No. 3960 (Weinberg/Johnson/Voss), which the committee also reported on this date.

SENATE HEALTH, HUMAN SERVICES AND SENIOR
CITIZENS COMMITTEE

STATEMENT TO

SENATE, No. 1684

STATE OF NEW JERSEY

DATED: OCTOBER 14, 2004

The Senate Health, Human Services and Senior Citizens Committee reports favorably Senate Bill No. 1684.

This bill would permit the State Medical Examiner to participate in research concerning sudden and unexpected deaths of infants and young children.

Although advances in genetics, biochemistry and other areas of medical research are yielding new information about the specific causes of sudden death in infancy and early childhood, sudden infant death syndrome (SIDS), remains a "rule-out" diagnosis for which the family learns what did not, rather than what did, cause the death of their child. Without knowing the actual cause of death, families are not able to determine if there is a genetic basis that places their other children at risk, and physicians are not able to prevent a death by prospectively diagnosing and treating a potentially fatal medical problem. The purpose of this bill, therefore, is to provide support to the families who lose children to SIDS and sudden and unexpected death and to help children in the future by determining the causes of these tragic deaths.

Specifically, the bill directs the State Medical Examiner, in consultation with the Commissioner of Health and Senior Services and the Sudden Child Death Autopsy Protocol Committee established pursuant to N.J.S.A.52:17B-88.10, to establish a protocol for participation by medical examiners in research activities concerning deaths of children three years of age and younger. The research shall include all autopsies in which the suspected cause of death of a child under one year of age is sudden infant death syndrome and the suspected cause of death of a child three years of age and younger is not considered to be an act of violence. The bill includes all deaths of children under the age of three to allow for more rigorous research that will include control groups.

The protocol shall authorize the State Medical Examiner, county medical examiner or other authorized person to harvest and transfer tissue samples to an approved research project prior to obtaining the consent of the parent or legal guardian of the deceased infant or young child, except that: the research project shall not be permitted to use

the tissue prior to obtaining the consent of the parent or guardian; and no tissue sample shall be harvested from a deceased infant or young child whose parent or legal guardian has objected to an autopsy in accordance with N.J.S.A.52:17B-88.2. The bill provides for the harvesting and transfer of tissue samples to an approved research project prior to obtaining the consent of the parent or legal guardian in recognition of the fact that much of today's research requires unique preservation and storing techniques of the tissue, which the medical examiner will not have available. Therefore, since the research project will have to assume responsibility for the preservation and storing of the tissue, there is not sufficient time for the medical examiner or researcher to obtain consent before the viable tissue must be transferred. The bill is clear, however, that before the research project can use the tissue, it must obtain the required consent.

The protocol shall, at a minimum, stipulate that:

- the research project first be approved by the institutional review board of the facility at which the research will be conducted, then by the Sudden Child Death Autopsy Protocol Committee, and finally by the Institutional Review Board of the New Jersey Department of Health and Senior Services;

- the research project delineate the information, other than the tissue sample, that will be required from the investigation of the death of the infant or young child;

- the research project develop a plan for the release by the State Medical Examiner or county medical examiner, as applicable, of a decedent's tissue as well as obtaining written consent for the use of the tissue and other identifying information from the parent or legal guardian of the deceased infant or young child;

- the research project develop a plan for the disposal of a decedent's tissue in the event that the parent or guardian does not give consent for use of the tissue, and in cases in which consent is given, upon completion of the research. The plan shall incorporate accepted procedures for disposal of surgical biopsies and biohazardous materials, and shall include procedures to inform the parent or guardian and the Sudden Child Death Autopsy Protocol Committee of the disposal plan;

- the research project reimburse the State Medical Examiner, county medical examiner or other authorized person participating in the research for reasonable costs incurred in harvesting, storing and providing tissue samples for the project. The estimated costs subject to reimbursement shall be reviewed and approved by the State Medical Examiner;

- the research project provide the State Medical Examiner and the Sudden Child Death Autopsy Protocol Committee with periodic updates on the status of the project; and

- the Sudden Child Death Autopsy Protocol Committee may terminate a research project that is not in compliance with the research project, as approved.

The bill directs the State Medical Examiner, county medical examiner or other authorized person, as applicable, to provide the research project with the tissue samples and copies of the autopsy reports and any related reports generated by the State Medical Examiner or county medical examiner concerning the subjects of the research (after the research project has obtained the required written consent of the parents or guardians). The information and tissue samples shall be used only by the research project for the purposes approved by the Sudden Child Death Autopsy Protocol Committee and as specified in the protocol, and shall not otherwise be divulged or made public so as to disclose the identity of any person to whom it relates. Under the provisions of the bill, the Sudden Child Death Autopsy Protocol Committee shall provide oversight on the approved research projects.

Finally, the bill provides immunity from civil liability to the State Medical Examiner, county medical examiner, their employees and other persons authorized by the State Medical Examiner to provide tissue samples and identifying information to the research project, and to the members of the Sudden Child Death Autopsy Protocol Committee, for any actions or omissions performed in good faith and in accordance with the provisions of this bill.

STATEMENT TO
SENATE, No. 1684

with Senate Floor Amendments
(Proposed By Senator CODEY)

ADOPTED: FEBRUARY 14, 2005

These amendments clarify that the State or county medical examiner shall not take and transfer tissue samples for research purposes from a deceased infant or young child whose parent or legal guardian has objected to an autopsy because it is contrary to the religious beliefs of the deceased infant or young child, in accordance with N.J.S.A.52:17B-88.2.

The amendments also replace the term "harvest" with the term "take."

ASSEMBLY, No. 3960

STATE OF NEW JERSEY 211th LEGISLATURE

INTRODUCED MAY 2, 2005

Sponsored by:

Assemblywoman LORETTA WEINBERG

District 37 (Bergen)

Assemblyman GORDON M. JOHNSON

District 37 (Bergen)

Assemblywoman JOAN VOSS

District 38 (Bergen)

Co-Sponsored by:

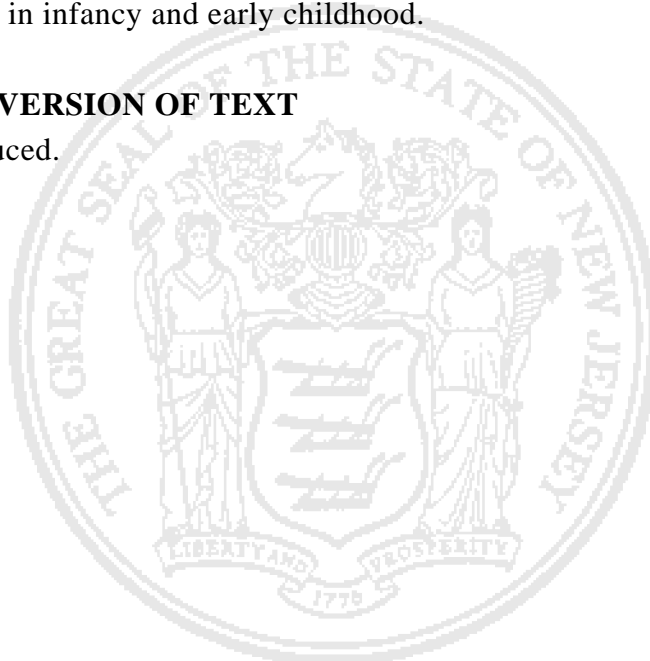
Assemblymen Gordon, Manzo and Merkt

SYNOPSIS

Authorizes State Medical Examiner to participate in research concerning sudden death in infancy and early childhood.

CURRENT VERSION OF TEXT

As introduced.



(Sponsorship Updated As Of: 6/10/2005)

A3960 WEINBERG, JOHNSON

2

1 AN ACT concerning research in sudden death in infancy and early
2 childhood and amending and supplementing P.L.2000, c.24.

3

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

6

7 1. Section 2 of P.L.2000, c.24 (C.52:17B-88.10) is amended to
8 read as follows:

9 2. a. The State Medical Examiner, in consultation with the
10 Commissioner of Health and Senior Services, shall develop
11 standardized protocols for autopsies performed in those cases in which
12 the suspected cause of death of a child under one year of age is sudden
13 infant death syndrome and in which the child is between one and three
14 years of age and the death is sudden and unexpected.

15 b. The State Medical Examiner shall establish a Sudden Child
16 Death Autopsy Protocol Committee to assist in developing and
17 reviewing the protocol. The committee shall include, but shall not be
18 limited to, the State Medical Examiner or his designee, the Assistant
19 Commissioner of the Division of Family Health Services in the
20 Department of Health and Senior Services or his designee, the
21 Director of the Division of Youth and Family Services in the
22 Department of Human Services or his designee, the director of the
23 SIDS Resource Center established pursuant to P.L.1987, c.331
24 (C.26:5D-4), an epidemiologist, a forensic pathologist, a pediatric
25 pathologist, a county medical examiner, a pediatrician who is
26 knowledgeable about sudden infant death syndrome and child abuse,
27 a law enforcement officer, an emergency medical technician or a
28 paramedic, a family member of a sudden infant death syndrome victim
29 and a family member of a sudden unexpected death victim who was
30 between one and three years of age at the time of death.

31 The committee shall annually review the protocol and make
32 recommendations to the State Medical Examiner to revise the
33 protocol, as appropriate.

34 c. The protocols shall include requirements and standards for scene
35 investigation, criteria for ascertaining the cause of death based on
36 autopsy, criteria for specific tissue sampling, and such other
37 requirements as the committee deems appropriate. The protocols shall
38 take into account nationally recognized standards for pediatric
39 autopsies.

40 The State Medical Examiner shall be responsible for ensuring that
41 the protocols are followed by all medical examiners and other persons
42 authorized to conduct autopsies in those cases in which the suspected
43 cause of death is sudden infant death syndrome or in which the child

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

Matter underlined thus is new matter.

1 is between one and three years of age and the death is sudden and
2 unexpected.

3 d. The protocols shall authorize the [medical examiner] State
4 Medical Examiner, county medical examiner or other authorized
5 person to take tissue samples for research purposes [if the parent,
6 parents or legal guardian of the deceased child provides written
7 consent for the taking of tissue samples for research purposes], as
8 provided in section 2 of P.L. , c. (C.)(pending before the
9 Legislature as this bill).

10 e. The sudden infant death syndrome autopsy protocol shall
11 provide that if the findings in the autopsy are consistent with the
12 definition of sudden infant death syndrome specified in the protocol,
13 the person who conducts the autopsy shall state on the death
14 certificate that sudden infant death syndrome is the cause of death.
15 (cf: P.L.2000, c.24, s.2)

16

17 2. (New section) The Legislature finds and declares that: advances
18 in genetics, biochemistry and other areas of medical research are
19 yielding new information about the specific causes of sudden death in
20 infancy and early childhood; these findings are of great importance
21 because the largest subgroup of these deaths, Sudden Infant Death
22 Syndrome, remains a "rule-out" diagnosis for which the family learns
23 what did not, rather than what did, cause the death of their child;
24 without knowing the actual cause, families are not able to determine
25 if there is a genetic basis that places their other children at risk, and
26 physicians are not able to prevent a death by prospectively diagnosing
27 and treating a potentially fatal medical problem; and if the State is to
28 meet its public health goal of reducing infant mortality, it is in the
29 public interest to accelerate efforts to identify actual causes of death
30 in infants and young children.

31 a. The State Medical Examiner, in consultation with the
32 Commissioner of Health and Senior Services and the Sudden Child
33 Death Autopsy Protocol Committee established pursuant to section 2
34 of P.L.2000, c.24 (C.52:17B-88.10) shall establish, pursuant to this
35 section, a protocol for participation by medical examiners in research
36 activities concerning deaths of children three years of age and younger.
37 The protocol shall be revised as necessary. The research shall include
38 all autopsies in which the suspected cause of death of a child under
39 one year of age is sudden infant death syndrome and the suspected
40 cause of death of a child three years of age and younger is not
41 considered a violent death pursuant to subsection a. of section 9 of
42 P.L.1967, c.234 (C.52:17B-86).

43 The protocol shall authorize the State Medical Examiner, county
44 medical examiner or other authorized person to take and transfer
45 tissue samples to an approved research project prior to obtaining the
46 consent of the parent or legal guardian of the deceased infant or young

1 child, but the research project shall not be permitted to use the tissue
2 prior to its obtaining consent as provided in paragraph (3) of this
3 subsection.

4 Notwithstanding the provisions of this section to the contrary, the
5 protocol shall provide that no tissue sample shall be taken from a
6 deceased infant or young child whose parent or legal guardian has
7 objected to an autopsy because it is contrary to the religious beliefs
8 of the deceased, in accordance with section 2 of P.L.1983, c.535
9 (C.52:17B-88.2).

10 The protocol shall, at a minimum, stipulate that:

11 (1) the research project first be approved by the institutional
12 review board of the facility at which the research shall be conducted,
13 then by the Sudden Child Death Autopsy Protocol Committee, and
14 finally by the Institutional Review Board of the New Jersey
15 Department of Health and Senior Services. If a research project is
16 submitted by the Department of Health and Senior Services, the final
17 review of the project shall be conducted by an independent review
18 board;

19 (2) the research project delineate the information, other than the
20 tissue sample, that will be required from the investigation of the death
21 of the infant or young child;

22 (3) the research project develop a plan for the release by the State
23 Medical Examiner or county medical examiner, as applicable, of a
24 decedent's tissue, as well as obtaining written consent for the use of
25 the tissue and other identifying information from the parent or legal
26 guardian of the deceased infant or young child;

27 (4) the research project develop a plan for the disposal of a
28 decedent's tissue in the event that the parent or guardian does not give
29 consent for use of the tissue, and in cases in which consent is given,
30 upon completion of the research. The plan shall incorporate accepted
31 procedures for disposal of surgical biopsies and biohazardous
32 materials, and shall include procedures to inform the parent or
33 guardian and the Sudden Child Death Autopsy Protocol Committee of
34 the disposal plan;

35 (5) the research project reimburse the State Medical Examiner,
36 county medical examiner or other authorized person participating in
37 the research for reasonable costs incurred in taking, storing and
38 providing tissue samples for the project. The estimated costs subject
39 to reimbursement shall be reviewed and approved by the State Medical
40 Examiner;

41 (6) the research project provide the State Medical Examiner and
42 the Sudden Child Death Autopsy Protocol Committee with periodic
43 updates on the status of the project; and

44 (7) the Sudden Child Death Autopsy Protocol Committee may
45 terminate a research project that is not in compliance with the research
46 project as approved pursuant to this subsection.

1 b. Upon receiving notification from the research project that the
2 research project has obtained written consent from the parent or legal
3 guardian of the deceased infant or young child for the use of tissue
4 samples and identifying information, the State Medical Examiner,
5 county medical examiner or other authorized person, as applicable,
6 shall provide the research project with copies of the autopsy reports
7 and any reports generated by the State Medical Examiner or county
8 medical examiner concerning the subject of the research.

9 c. The information and tissue samples provided by the State
10 Medical Examiner, county medical examiner or other authorized
11 person to the research project shall be used by the research project
12 only for the purposes approved by the Sudden Child Death Autopsy
13 Protocol Committee and as specified in the protocol, and shall not
14 otherwise be divulged or made public so as to disclose the identity of
15 any person to whom they relate. The information provided to the
16 research project shall not be considered a public record pursuant to
17 P.L.1963, c.73 (C.47:1A-1 et seq.) or P.L.2001, c.404 (C.47:1A-5 et
18 al.).

19 d. The Sudden Child Death Autopsy Protocol Committee shall
20 oversee the approved research projects.

21 e. The State Medical Examiner, county medical examiner, their
22 employees and other persons authorized by the State Medical
23 Examiner to provide tissue samples and identifying information to the
24 research project, and the members of the Sudden Child Death
25 Autopsy Protocol Committee shall not be liable for civil damages as
26 the result of any actions or omissions performed in good faith and in
27 accordance with the provisions of this act.

28

29 3. This act shall take effect on the 60th day after enactment.

30

31

32

STATEMENT

33

34 This bill would permit the State Medical Examiner to participate in
35 research concerning sudden and unexpected deaths of infants and
36 young children.

37 Although advances in genetics, biochemistry and other areas of
38 medical research are yielding new information about the specific
39 causes of sudden death in infancy and early childhood, sudden infant
40 death syndrome (SIDS), remains a "rule-out" diagnosis for which the
41 family learns what did not, rather than what did, cause the death of
42 their child. Without knowing the actual cause of death, families are
43 not able to determine if there is a genetic basis that places their other
44 children at risk, and physicians are not able to prevent a death by
45 prospectively diagnosing and treating a potentially fatal medical
46 problem. The purpose of this bill, therefore, is to provide support to

1 the families who lose children to SIDS and sudden and unexpected
2 death and to help children in the future by determining the causes of
3 these tragic deaths.

4 Specifically, the bill directs the State Medical Examiner, in
5 consultation with the Commissioner of Health and Senior Services and
6 the Sudden Child Death Autopsy Protocol Committee established
7 pursuant to N.J.S.A.52:17B-88.10, to establish a protocol for
8 participation by medical examiners in research activities concerning
9 deaths of children three years of age and younger. The research shall
10 include all autopsies in which the suspected cause of death of a child
11 under one year of age is sudden infant death syndrome and the
12 suspected cause of death of a child three years of age and younger is
13 not considered to be an act of violence. The bill includes all deaths of
14 children under the age of three to allow for more rigorous research
15 that will include control groups.

16 The protocol shall authorize the State Medical Examiner, county
17 medical examiner or other authorized person to take and transfer
18 tissue samples to an approved research project prior to obtaining the
19 consent of the parent or legal guardian of the deceased infant or young
20 child, except that: the research project shall not be permitted to use
21 the tissue prior to obtaining the consent of the parent or guardian; and
22 no tissue sample shall be taken from a deceased infant or young child
23 whose parent or legal guardian has objected to an autopsy in
24 accordance with N.J.S.A.52:17B-88.2 because it is contrary to the
25 religious beliefs of the deceased. The bill provides for the taking and
26 transfer of tissue samples to an approved research project prior to
27 obtaining the consent of the parent or legal guardian in recognition of
28 the fact that much of today's research requires unique preservation and
29 storing techniques of the tissue, which the medical examiner will not
30 have available. Therefore, since the research project will have to
31 assume responsibility for the preservation and storing of the tissue,
32 there is not sufficient time for the medical examiner or researcher to
33 obtain consent before the viable tissue must be transferred. The bill is
34 clear, however, that before the research project can use the tissue, it
35 must obtain the required consent.

36 The protocol shall, at a minimum, stipulate that:

37 - the research project first be approved by the institutional review
38 board of the facility at which the research will be conducted, then by
39 the Sudden Child Death Autopsy Protocol Committee, and finally by
40 the Institutional Review Board of the New Jersey Department of
41 Health and Senior Services;

42 - the research project delineate the information, other than the
43 tissue sample, that will be required from the investigation of the death
44 of the infant or young child;

45 - the research project develop a plan for the release by the State
46 Medical Examiner or county medical examiner, as applicable, of a

1 decedent's tissue as well as obtaining written consent for the use of the
2 tissue and other identifying information from the parent or legal
3 guardian of the deceased infant or young child;

4 - the research project develop a plan for the disposal of a decedent's
5 tissue in the event that the parent or guardian does not give consent
6 for use of the tissue, and in cases in which consent is given, upon
7 completion of the research. The plan shall incorporate accepted
8 procedures for disposal of surgical biopsies and biohazardous
9 materials, and shall include procedures to inform the parent or
10 guardian and the Sudden Child Death Autopsy Protocol Committee of
11 the disposal plan;

12 - the research project reimburse the State Medical Examiner, county
13 medical examiner or other authorized person participating in the
14 research for reasonable costs incurred in taking, storing and providing
15 tissue samples for the project. The estimated costs subject to
16 reimbursement shall be reviewed and approved by the State Medical
17 Examiner;

18 - the research project provide the State Medical Examiner and the
19 Sudden Child Death Autopsy Protocol Committee with periodic
20 updates on the status of the project; and

21 - the Sudden Child Death Autopsy Protocol Committee may
22 terminate a research project that is not in compliance with the research
23 project, as approved.

24 The bill directs the State Medical Examiner, county medical
25 examiner or other authorized person, as applicable, to provide the
26 research project with the tissue samples and copies of the autopsy
27 reports and any related reports generated by the State Medical
28 Examiner or county medical examiner concerning the subjects of the
29 research (after the research project has obtained the required written
30 consent of the parents or guardians). The information and tissue
31 samples shall be used only by the research project for the purposes
32 approved by the Sudden Child Death Autopsy Protocol Committee and
33 as specified in the protocol, and shall not otherwise be divulged or
34 made public so as to disclose the identity of any person to whom it
35 relates. Under the provisions of the bill, the Sudden Child Death
36 Autopsy Protocol Committee shall provide oversight on the approved
37 research projects.

38 Finally, the bill provides immunity from civil liability to the State
39 Medical Examiner, county medical examiner, their employees and
40 other persons authorized by the State Medical Examiner to provide
41 tissue samples and identifying information to the research project, and
42 to the members of the Sudden Child Death Autopsy Protocol
43 Committee, for any actions or omissions performed in good faith and
44 in accordance with the provisions of this bill.

ASSEMBLY HEALTH AND HUMAN SERVICES COMMITTEE

STATEMENT TO

ASSEMBLY, No. 3960

STATE OF NEW JERSEY

DATED: MAY 2, 2005

The Assembly Health and Human Services Committee reports favorably Assembly Bill No. 3960.

This bill would permit the State Medical Examiner to participate in research concerning sudden and unexpected deaths of infants and young children.

The purpose of this bill is to provide support to the families who lose children to sudden infant death syndrome (SIDS) and sudden and unexpected death and to help children in the future by determining the causes of these tragic deaths.

The bill provides specifically as follows:

- C The State Medical Examiner, in consultation with the Commissioner of Health and Senior Services and the Sudden Child Death Autopsy Protocol Committee established pursuant to N.J.S.A.52:17B-88.10, is to establish a protocol for participation by medical examiners in research activities concerning deaths of children three years of age and younger. The research would include all autopsies in which the suspected cause of death of a child under one year of age is SIDS and the suspected cause of death of a child three years of age and younger is not considered to be an act of violence. The bill includes all deaths of children under the age of three to allow for more rigorous research that will include control groups.
- C The protocol is to authorize the State Medical Examiner, county medical examiner or other authorized person to take and transfer tissue samples to an approved research project prior to obtaining the consent of the parent or legal guardian of the deceased infant or young child, except that: the research project is not permitted to use the tissue prior to obtaining the consent of the parent or guardian; and no tissue sample is to be taken from a deceased infant or young child whose parent or legal guardian has objected to an autopsy in accordance with N.J.S.A.52:17B-88.2 because it is contrary to the religious beliefs of the deceased. (The bill provides for the taking and transfer of tissue samples to an approved research project prior to obtaining the consent of the parent or legal guardian in recognition of the fact that much of today's research requires unique preservation and storing techniques of the tissue, which the medical examiner will not have

available. Since the research project will have to assume responsibility for the preservation and storing of the tissue, there is not sufficient time for the medical examiner or researcher to obtain consent before the viable tissue must be transferred; however, the bill clearly requires that the research project obtain the required consent before it can use the tissue.)

C The protocol, at a minimum, is to stipulate that:

-- the research project first be approved by the institutional review board of the facility at which the research will be conducted, then by the Sudden Child Death Autopsy Protocol Committee, and finally by the Institutional Review Board of the New Jersey Department of Health and Senior Services;

-- the research project delineate the information, other than the tissue sample, that will be required from the investigation of the death of the infant or young child;

-- the research project develop a plan for the release by the State Medical Examiner or county medical examiner, as applicable, of a decedent's tissue, as well as obtaining written consent for the use of the tissue and other identifying information from the parent or legal guardian of the deceased infant or young child;

-- the research project develop a plan for the disposal of a decedent's tissue in the event that the parent or guardian does not give consent for use of the tissue, and in cases in which consent is given, upon completion of the research, which plan must incorporate accepted procedures for disposal of surgical biopsies and biohazardous materials, and include procedures to inform the parent or guardian and the Sudden Child Death Autopsy Protocol Committee of the disposal plan;

-- the research project reimburse the State Medical Examiner, county medical examiner or other authorized person participating in the research for reasonable costs incurred in taking, storing and providing tissue samples for the project, with the estimated costs subject to reimbursement to be reviewed and approved by the State Medical Examiner;

-- the research project provide the State Medical Examiner and the Sudden Child Death Autopsy Protocol Committee with periodic updates on the status of the project; and

-- the Sudden Child Death Autopsy Protocol Committee may terminate a research project that is not in compliance with the research project, as approved.

C The State Medical Examiner, county medical examiner or other authorized person, as applicable, is to provide the research project with the tissue samples and copies of the autopsy reports and any related reports generated by the State Medical Examiner or county medical examiner concerning the subjects of the research (after the research project has obtained the required written consent of the parents or guardians). The information and tissue samples are to be used only by the research project for the purposes approved by

the Sudden Child Death Autopsy Protocol Committee and as specified in the protocol, and are not otherwise to be divulged or made public so as to disclose the identity of any person to whom they relate. The Sudden Child Death Autopsy Protocol Committee is to oversee the approved research projects.

- C Finally, the bill provides immunity from civil liability to the State Medical Examiner, county medical examiner, their employees and other persons authorized by the State Medical Examiner to provide tissue samples and identifying information to the research project, and to the members of the Sudden Child Death Autopsy Protocol Committee, for any actions or omissions performed in good faith and in accordance with the provisions of this bill.
- C The bill takes effect on the 60th day after enactment.

This bill is identical to Senate Bill No. 1684 (1R) (Codey), which the committee also reported on this date.