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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IS 11/8/07

P.L. 2005, CHAPTER 227, ***approved September 22, 2005***
Senate, No. 1684 ***(First Reprint)***

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

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

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

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

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

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

c. The protocols shall include requirements and standards for scene investigation, criteria for ascertaining the cause of death based on autopsy, criteria for specific tissue sampling, and such other requirements as the committee deems appropriate. The protocols shall take into account nationally recognized standards for pediatric 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 <u>thus</u> is new matter.
Matter enclosed in superscript numerals has been adopted as follows:
[1] Senate floor amendments adopted February 14, 2005.

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

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

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

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

2. (New section) The Legislature finds and declares that: 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; these findings are of great importance because the largest subgroup of these deaths, Sudden Infant Death Syndrome, 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, 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; and if the State is to meet its public health goal of reducing infant mortality, it is in the public interest to accelerate efforts to identify actual causes of death in infants and young children.

a. 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 section 2 of P.L.2000, c.24 (C.52:17B-88.10) shall establish, pursuant to this section, a protocol for participation by medical examiners in research activities concerning deaths of children three years of age and younger. The protocol shall be revised as necessary. 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 a violent death pursuant to subsection a. of section 9 of P.L.1967, c.234 (C.52:17B-86).

The protocol shall authorize the State Medical Examiner, county medical examiner or other authorized person to [1]**[**harvest**]** take[1] 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, [1]**[**except that:**]**but[1] the research project shall not be permitted to use the tissue prior to its obtaining consent as provided in paragraph (3) of this subsection[1]**[**; and no**]**.

Notwithstanding the provisions of this section to the contrary, the protocol shall provide that no[1] tissue sample shall be [1]**[**harvested**]** taken[1] from a deceased infant or young child whose parent or legal guardian has objected to an autopsy [1]because it is contrary to the religious beliefs of the deceased,[1] in accordance with section 2 of P.L.1983, c.535 (C.52:17B-88.2).

The protocol shall, at a minimum, stipulate that:

(1) the research project first be approved by the institutional review board of the facility at which the research shall 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. If a research project is submitted by the Department of Health and Senior Services, the final review of the project shall be conducted by an independent review board;

(2) 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;

(3) 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;

(4) 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;

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

(6) 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

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

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

c. The information and tissue samples provided by the State Medical Examiner, county medical examiner or other authorized person to the research project shall be used by the research project only 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 they relate. The information provided to the research project shall not be considered a public record pursuant to P.L.1963, c.73 (C.47:1A-1 et seq.) or P.L.2001, c.404 (C.47:1A-5 et al.).

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

e. 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 the members of the Sudden Child Death Autopsy Protocol Committee shall not be liable for civil damages as the result of any actions or omissions performed in good faith and in accordance with the provisions of this act.

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

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.

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

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

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

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

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

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

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

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

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Matter underlined <u>thus</u> is new matter.

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

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

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

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

2. (New section) The Legislature finds and declares that: 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; these findings are of great importance because the largest subgroup of these deaths, Sudden Infant Death Syndrome, 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, 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; and if the State is to meet its public health goal of reducing infant mortality, it is in the public interest to accelerate efforts to identify actual causes of death in infants and young children.

a. 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 section 2 of P.L.2000, c.24 (C.52:17B-88.10) shall establish, pursuant to this section, a protocol for participation by medical examiners in research activities concerning deaths of children three years of age and younger. The protocol shall be revised as necessary. 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 a violent death pursuant to subsection a. of section 9 of P.L.1967, c.234 (C.52:17B-86).

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 its obtaining consent as provided in paragraph (3) of this subsection; 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 section 2 of P.L.1983, c.535 (C.52:17B-88.2).

The protocol shall, at a minimum, stipulate that:

(1) the research project first be approved by the institutional review board of the facility at which the research shall 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. If a research project is submitted by the Department of Health and Senior Services, the final review of the project shall be conducted by an independent review board;

(2) 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;

(3) 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;

(4) 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;

(5) 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;

(6) 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

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

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

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

c. The information and tissue samples provided by the State Medical Examiner, county medical examiner or other authorized person to the research project shall be used by the research project only 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 they relate. The information provided to the research project shall not be considered a public record pursuant to P.L.1963, c.73 (C.47:1A-1 et seq.) or P.L.2001, c.404 (C.47:1A-5 et al.).

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

e. 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 the members of the Sudden Child Death Autopsy Protocol Committee shall not be liable for civil damages as the result of any actions or omissions performed in good faith and in accordance with the provisions of this act.

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

STATEMENT

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

Specifically, the bill provides that:

-- 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, shall 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 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 shall 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 shall 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 State Medical Examiner, county medical examiner or other authorized person, as applicable, shall 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 provided by the State Medical Examiner, county medical examiner or other authorized person to the research project 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.

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

-- 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 the members of the Sudden Child Death Autopsy Protocol Committee shall not be liable for civil damages as the result of any actions or omissions performed in good faith and in 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:

- 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.
- 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.

- 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.
- 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)

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

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

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

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

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

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

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

The State Medical Examiner shall be responsible for ensuring that the protocols are followed by all medical examiners and other persons authorized to conduct autopsies in those cases in which the suspected 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 <u>thus</u> is new matter.

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

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

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

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

2. (New section) The Legislature finds and declares that: 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; these findings are of great importance because the largest subgroup of these deaths, Sudden Infant Death Syndrome, 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, 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; and if the State is to meet its public health goal of reducing infant mortality, it is in the public interest to accelerate efforts to identify actual causes of death in infants and young children.

a. 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 section 2 of P.L.2000, c.24 (C.52:17B-88.10) shall establish, pursuant to this section, a protocol for participation by medical examiners in research activities concerning deaths of children three years of age and younger. The protocol shall be revised as necessary. 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 a violent death pursuant to subsection a. of section 9 of P.L.1967, c.234 (C.52:17B-86).

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

Notwithstanding the provisions of this section to the contrary, the protocol shall provide that no tissue sample shall be taken 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, in accordance with section 2 of P.L.1983, c.535 (C.52:17B-88.2).

The protocol shall, at a minimum, stipulate that:

(1) the research project first be approved by the institutional review board of the facility at which the research shall 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. If a research project is submitted by the Department of Health and Senior Services, the final review of the project shall be conducted by an independent review board;

(2) 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;

(3) 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;

(4) 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;

(5) 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. The estimated costs subject to reimbursement shall be reviewed and approved by the State Medical Examiner;

(6) 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

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

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

c. The information and tissue samples provided by the State Medical Examiner, county medical examiner or other authorized person to the research project shall be used by the research project only 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 they relate. The information provided to the research project shall not be considered a public record pursuant to P.L.1963, c.73 (C.47:1A-1 et seq.) or P.L.2001, c.404 (C.47:1A-5 et al.).

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

e. 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 the members of the Sudden Child Death Autopsy Protocol Committee shall not be liable for civil damages as the result of any actions or omissions performed in good faith and in accordance with the provisions of this act.

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

STATEMENT

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 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 shall not be permitted to use the tissue prior to obtaining the consent of the parent or guardian; and no tissue sample shall 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. 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 taking, 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.

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:

- 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.
- 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.

- 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.
- 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.