



# Senate

General Assembly

**File No. 133**

February Session, 2008

Substitute Senate Bill No. 464

*Senate, March 25, 2008*

The Committee on Public Health reported through SEN. HANDLEY of the 4th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

## ***AN ACT CONCERNING STEM CELL RESEARCH.***

Be it enacted by the Senate and House of Representatives in General Assembly convened:

1 Section 1. Section 19a-32d of the general statutes is repealed and the  
2 following is substituted in lieu thereof (*Effective October 1, 2008*):

3 (a) As used in sections 19a-32d to 19a-32g, inclusive, and section 4-  
4 28e:

5 (1) "Institutional review committee" means the local institutional  
6 review committee specified in 21 USC 360j(g)(3)(A)(i), as amended  
7 from time to time, and, when applicable, an institutional review board  
8 established in accordance with the requirements of 45 CFR 46, Subpart  
9 A, as amended from time to time.

10 (2) "Cloning of a human being" means inducing or permitting a  
11 replicate of a living human being's complete set of genetic material to  
12 develop after gastrulation commences.

13 (3) "Gastrulation" means the process immediately following the  
14 blastula state when the hollow ball of cells representing the early  
15 embryo undergoes a complex and coordinated series of movements  
16 that results in the formation of the three primary germ layers, the  
17 ectoderm, mesoderm and endoderm.

18 (4) "Embryonic stem cells" means cells created through the joining of  
19 a human egg and sperm or through nuclear transfer that are  
20 sufficiently undifferentiated such that they cannot be identified as  
21 components of any specialized cell type.

22 (5) "Embryonic stem cell research oversight committee" means a  
23 committee established in accordance with the National Academies'  
24 Guidelines for Human Embryonic Stem Cell Research, as amended  
25 from time to time.

26 [(5)] (6) "Nuclear transfer" means the replacement of the nucleus of a  
27 human egg with a nucleus from another human cell.

28 [(6)] (7) "Eligible institution" means (A) a nonprofit, tax-exempt  
29 academic institution of higher education, (B) a hospital that conducts  
30 biomedical research, or (C) any entity that conducts biomedical  
31 research or embryonic or human adult stem cell research.

32 (b) No person shall knowingly (1) engage or assist, directly or  
33 indirectly, in the cloning of a human being, (2) implant human  
34 embryos created by nuclear transfer into a uterus or a device similar to  
35 a uterus, or (3) facilitate human reproduction through clinical or other  
36 use of human embryos created by nuclear transfer. Any person who  
37 violates the provisions of this subsection shall be fined not more than  
38 one hundred thousand dollars or imprisoned not more than ten years,  
39 or both. Each violation of this subsection shall be a separate and  
40 distinct offense.

41 (c) (1) A physician or other health care provider who is treating a  
42 patient for infertility shall provide the patient with timely, relevant  
43 and appropriate information sufficient to allow that person to make an

44 informed and voluntary choice regarding the disposition of any  
45 embryos or embryonic stem cells remaining following an infertility  
46 treatment.

47 (2) A patient to whom information is provided pursuant to  
48 subdivision (1) of this subsection shall be presented with the option of  
49 storing, donating to another person, donating for research purposes, or  
50 otherwise disposing of any unused embryos or embryonic stem cells.

51 (3) A person who elects to donate for stem cell research purposes  
52 any human embryos or embryonic stem cells remaining after receiving  
53 infertility treatment, or unfertilized human eggs or human sperm shall  
54 provide written consent for that donation and shall not receive direct  
55 or indirect payment for such human embryos, embryonic stem cells,  
56 unfertilized human eggs or human sperm. Consent obtained pursuant  
57 to this subsection shall, at a minimum, conform to the National  
58 Academies' Guidelines for Human Embryonic Stem Cell Research, as  
59 amended from time to time.

60 (4) Any person who violates the provisions of this subsection shall  
61 be fined not more than fifty thousand dollars or imprisoned not more  
62 than five years, or both. Each violation of this subsection shall be a  
63 separate and distinct offense.

64 (d) A person may conduct research involving embryonic stem cells,  
65 provided (1) the research is conducted with full consideration for the  
66 ethical and medical implications of such research, (2) the research is  
67 conducted before gastrulation occurs, (3) prior to conducting such  
68 research, the person provides documentation to the Commissioner of  
69 Public Health [documentation] in a form and manner prescribed by the  
70 commissioner verifying: [that] (A) That any human embryos,  
71 embryonic stem cells, unfertilized human eggs or human sperm used  
72 in such research have been donated voluntarily in accordance with the  
73 provisions of subsection (c) of this section, [on a form and in the  
74 manner prescribed by the Commissioner of Public Health] or (B) if any  
75 embryonic stem cells have been derived outside the state of  
76 Connecticut, that such stem cells have been acceptably derived as

77 provided in the National Academies' Guidelines for Human  
78 Embryonic Stem Cell Research, as amended from time to time, (4) the  
79 general research program under which such research is conducted is  
80 reviewed and approved by an institutional review committee, as  
81 required under federal law, [and] (5) the specific protocol used to  
82 derive stem cells from an embryo is reviewed and approved by an  
83 institutional review committee, and (6) all activities involving  
84 embryonic stem cells are overseen by an embryonic stem cell research  
85 oversight committee.

86 (e) The Commissioner of Public Health shall enforce the provisions  
87 of this section and may adopt regulations, in accordance with the  
88 provisions of chapter 54, relating to the administration and  
89 enforcement of this section. The commissioner may request the  
90 Attorney General to petition the Superior Court for such order as may  
91 be appropriate to enforce the provisions of this section.

92 (f) Any person who conducts research involving embryonic stem  
93 cells in violation of the requirements of subdivision (2) of subsection  
94 (d) of this section shall be fined not more than fifty thousand dollars,  
95 or imprisoned not more than five years, or both.

96 Sec. 2. Subsection (e) of section 19a-32g of the 2008 supplement to  
97 the general statutes is repealed and the following is substituted in lieu  
98 thereof (*Effective October 1, 2008*):

99 (e) All members of the committee shall become and remain fully  
100 cognizant of the National [Academies] Academies' Guidelines [For] for  
101 Human Embryonic Stem Cell Research, as [from time to time]  
102 amended from time to time, and [the] shall utilize said guidelines to  
103 evaluate each grant-in-aid application. The committee may make  
104 recommendations to the Stem Cell Research Advisory Committee and  
105 the Commissioner of Public Health concerning the adoption of said  
106 guidelines, in whole or in part, in the form of regulations adopted  
107 pursuant to chapter 54.

This act shall take effect as follows and shall amend the following sections:		
Section 1	October 1, 2008	19a-32d
Sec. 2	October 1, 2008	19a-32g(e)

**Statement of Legislative Commissioners:**

In subsection (a) of section 1, the reference to the 2008 supplement to the general statutes following the string citation was deleted for clarity. Subdivision (3) of subsection (d) of section 1 was redrafted with subparagraph indicators (A) and (B) for added clarity.

**PH**      *Joint Favorable Subst.-LCO*

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The following fiscal impact statement and bill analysis are prepared for the benefit of members of the General Assembly, solely for the purpose of information, summarization, and explanation, and do not represent the intent of the General Assembly or either chamber thereof for any purpose:

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***OFA Fiscal Note***

***State Impact:*** None

***Municipal Impact:*** None

***Explanation***

No fiscal impact is anticipated to result given passage of this bill. It should be noted that the University of Connecticut presently has an embryonic stem cell research oversight committee in place.

***The Out Years***

***State Impact:*** None

***Municipal Impact:*** None

**OLR Bill Analysis****sSB 464*****AN ACT CONCERNING STEM CELL RESEARCH. AN ACT CONCERNING STEM CELL RESEARCH.*****SUMMARY:**

This bill makes changes to Connecticut's existing stem cell research law to reflect the acknowledgment of and compliance with, the "National Academies' Guidelines for, Human Embryonic Stem Cell Research" (see BACKGROUND). The bill (1) amends the consent requirements for prospective donors of embryos, (2) establishes standards to allow the use of human embryonic stem cell lines derived outside of Connecticut, (3) requires that all human embryonic stem cell research conducted in the state be overseen by embryonic stem cell review oversight committees, and (4) requires the state's Stem Cell Research Peer Review Committee members to utilize the guidelines when evaluating grant applications.

EFFECTIVE DATE: October 1, 2008

**COMPLIANCE WITH NATIONAL ACADEMIES' GUIDELINES*****Consent for Donation***

By law, a person choosing to donate for stem cell research purposes any human embryos or embryonic stem cells remaining after undergoing fertility treatment, or unfertilized human eggs or human sperm must give written consent for the donation and cannot receive any direct or indirect payment for them.

The bill requires that consent for such donations conform to the National Academies' guidelines.

Under the guidelines, consent for donation should be obtained from each donor at the time of donation. Even those who have given prior

indication of their intent to donate to research any embryos remaining after clinical care should nonetheless give informed consent at the time of donation. Donors should be informed that they retain the right to withdraw consent until the embryos are actually used in cell line derivation.

### ***Research on Stem Cells Derived Outside of Connecticut***

The bill allows human embryonic stem cell research on stem cells that have been derived outside of Connecticut and have been acceptably derived as provided in the guidelines. This would have the effect of allowing the use in Connecticut of human embryonic stem cells lines derived elsewhere (e.g., the United Kingdom, Canada, the California Institute for Regenerative Medicine). Under the guidelines, (1) the cell lines must have the donation protocol reviewed by an Institutional Review Board, or if the lines were developed outside the United States, a substantially equivalent oversight body; (2) there must be informed and voluntary consent; (3) there must have been no payment for donation; and (4) the donation must be legal in the relevant jurisdiction.

### ***Embryonic Stem Cell Research Oversight Committees (ESCROs)***

The bill requires that all human embryonic stem cell research performed in Connecticut be overseen by an ESCRO. The bill defines such a committee as one established according to the National Academies' guidelines.

The guidelines make clear that activities related to human embryonic stem cell research should be overseen by an ESCRO. Such committees, according to the guidelines, can be internal to a single institution or established jointly with one or more other institutions. The guidelines give ESCROs the following responsibilities:

1. provide oversight over all issues related to derivation and use of human embryonic stem cell lines,
2. review and approve the scientific merit of research protocols,

3. review compliance of all in-house human embryonic stem cell research with all relevant regulations and these guidelines,
4. maintain registries of human embryonic stem cell research conducted at the institution and cell lines derived or imported by institutional investigators, and
5. facilitate education of investigators involved in human embryonic stem cell research.

Although an ESCRO may overlap with other oversight committees, it should not be a subcommittee of an institutional review board according to the guidelines.

### ***Stem Cell Research Peer Review Committee***

Under current law, the Department of Public Health (DPH) commissioner appoints a Stem Cell Research Peer Review Committee of up to 15 members. The committee reviews all applications for grants and makes recommendations to DPH and the existing Stem Cell Research Advisory Committee concerning the ethical and scientific merit of each application. Peer review committee members must be aware of the National Academies' guidelines.

The bill specifies that the peer review committee must utilize the guidelines to evaluate each grant application.

## **BACKGROUND**

### ***National Academies***

The National Academies is an independent organization chartered by Congress to advise the government on scientific, engineering, and health matters. In April 2005, it released guidelines and recommendations for human embryonic stem cell research. These guidelines are intended for use by the scientific community, including researchers in academic, industry, or other private sector organizations.

The guidelines are amended from time to time. The National

Academies called for the establishment of ESCROs in its 2005 guidelines. The guidelines committee believes that all research institutions engaged in human embryonic stem cell research should create and maintain these committees at the local level. The composition and responsibilities of ESCRO committees was further clarified in February 2007 amendments to the guidelines.

**COMMITTEE ACTION**

Public Health Committee

Joint Favorable

Yea 28 Nay 0 (03/07/2008)