

**SENATE . . . . . No. 151**

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The Commonwealth of Massachusetts

PRESENTED BY:

*Cynthia S. Creem*

*To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:*

The undersigned legislators and/or citizens respectfully petition for the passage of the accompanying:

An Act clarifying chapter 111L - biotechnology.

PETITION OF:

NAME:

*Cynthia S. Creem*

DISTRICT/ADDRESS:

- 
- 

*[District]*

**SENATE . . . . . No. 151**

By Ms. Creem, a petition (accompanied by bill, Senate, No. 151) of Cynthia S. Creem for legislation to clarify Chaoter111L-biotechnology. Economic Development and Emerging Technologies.

[SIMILAR MATTER FILED IN PREVIOUS SESSION

SEE

□ □ SENATE  
□ , NO. 193 OF 2009-2010.]

**The Commonwealth of Massachusetts**

An Act clarifying chapter 111L - biotechnology.

*Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:*

1 SECTION 1. Paragraph (c) of Section 1 of Chapter 111L of the General Laws  
2 as appearing in the 2006 Official Edition, is hereby amended by striking in lines 15-16 the words  
3 “placental and umbilical cord cells and human adult stem cells”, and inserting at the end of this  
4 same paragraph the following sentence: Nothing in this chapter shall prohibit research or clinical  
5 applications involving human adult stem cells, umbilical cord cells, amniotic fluid cells or  
6 placental cells.

7 SECTION 2. Section 2 of Chapter 111L of the General Laws as appearing in  
8 the 2006 Official Edition, is hereby amended by striking the definition of "Donated to research"  
9 in lines 7-14 and inserting in place thereof the following:

10 “Donated to research”, when, in the absence of valuable consideration and after  
11 fulfillment of the requirements of informed consent, the persons from whose gametes or cells the  
12 pre-implantation embryo has originated or will originate gives the pre-implantation embryo,  
13 gametes or cells to another person; provided, however, that the recipient shall not transfer the  
14 extant or resultant pre-implantation embryo to a uterus or uterine-like environment or nurture the  
15 pre-implantation embryo beyond 14 days of development.

16 SECTION 3. Said Section 2 is hereby further amended by inserting the  
17 following new definitions:

18 “ESCRO committee”, means an Embryonic Stem Cell Research Oversight committee  
19 that is constituted and operated in a manner consistent with the guidelines of either the National  
20 Academies of Sciences or the International Society for Stem Cell Research.’

21 "Reasonable costs", for purposes of reimbursing oocyte donors, may include, but are not  
22 limited to, any of the following types of costs if approved by an institutional review board:  
23 travel, temporary lodging, childcare, medical care, health insurance (if limited to co-pays and  
24 deductibles and the purchase of time-limited accident insurance coverage for complications  
25 arising directly from the egg donation process) and actual lost wages, and any other types of such  
26 costs as may be approved by such institutional review board.

27 SECTION 4. Said Section 2 is further amended by striking the definition of  
28 "Valuable consideration" in lines 90-93 and replacing it with the following:

29 “Valuable consideration”, any consideration beyond reimbursement for reasonable costs  
30 incurred in connection with the donation, removal, processing, disposal, preservation, quality  
31 control or storage of gametes or embryos for research purposes.

32 SECTION 5. Section 3(a) of Chapter 111L of the General Laws as appearing  
33 in the 2006 Official Edition, shall be deleted and new language inserted as follows:

34 Research and clinical applications involving the derivation and use of human embryonic  
35 stem cells from materials donated to research, including, without limitation, pre-implantation  
36 embryos, whether created by the method of fertilization or by somatic cell nuclear transfer,  
37 parthenogenesis or other asexual means, gametes, somatic cells and parthenotes shall be  
38 permitted.

39 SECTION 6. Section 3 (b) of Chapter 111L of the General Laws as appearing  
40 in the 2006 Official Edition, shall be amended by inserting in line 9 after the words “duly  
41 authorized institutional review board” the following:

42 or ESCRO committee; provided that if such research is approved only by an ESCRO  
43 committee, documentation shall be maintained by the ESCRO committee that an institutional  
44 review board or another equivalent body determined that any human embryos, cells or gametes  
45 to be used in the research were donated to research, as defined in section 2 or in a manner  
46 permitted under the laws of the state or foreign country where the donation to research occurred  
47 and in a manner otherwise acceptable to the ESCRO.

48 And said section 3 (b) is further, by inserting in lines 9-10 after the words “approval of  
49 the institutional review board”, the following: “or ESCRO committee”.

50 And further, by inserting in line 13 after the words “permanent record by the board”, the  
51 following: “or ESCRO committee”.

52 And further, by inserting in line 14 after the words “for which the board”, the following:  
53 “or ESCRO committee”.

54 SECTION 7. Section 8(c) of Chapter 111L of the General Laws as appearing  
55 in the 2006 Official Edition, shall be amended by deleting in lines 12- 13 the words: “or  
56 cadaveric tissue”; and by inserting in line 17 after the words “regulate the use” the following: “or  
57 study”

58 SECTION 8. Section 9(e) of Chapter 111L of the General Laws as appearing  
59 in the 2006 Official Edition, shall be amended by deleting all language following the words “not  
60 less than twice a year”; and by inserting language as follows:

61 Notwithstanding section 11A 1/2 of chapter 30A of the General Laws, the council may  
62 conduct its meetings by telephone conference or similar communications equipment which  
63 allows all persons participating in the meeting to hear each other at the same time. Participation  
64 by such means shall constitute presence in person at a meeting. Notice of a meeting held in this  
65 manner shall be provided in accordance with the requirements of section 11A 1/2 of chapter 30A  
66 of the General Laws, and shall state that members of the public will be afforded a location, as  
67 specified in the notice, where they may attend the meeting by conference telephone or similar  
68 communications equipment.

69 SECTION 9. Section 10(f) of Chapter 111L of the General Laws as appearing  
70 in the 2006 Official Edition, shall be amended by deleting all language after the words “and (ii)”  
71 in line 74 and inserting the following language: provides documentation to the department  
72 demonstrating that the institution has either an institutional review board or ESCRO committee  
73 or both, or provides a copy of a contract between the institution and either a private or public  
74 institutional review board or ESCRO committee, as applicable, which shall provide any review  
75 required by this chapter. Any institution which submits an application and meets the  
76 requirements for a certificate of registration pursuant to this section shall not have the certificate  
77 of registration unreasonably withheld. A certificate may be withheld if the department  
78 determines that the applicant institution has violated subsection (m).

79 SECTION 10. Section 10(i) of Chapter 111L of the General Laws as  
80 appearing in the 2006 Official Edition, shall be amended by deleting all language following the  
81 words “pursuant to subsection (f)” and inserting the following language:

82 shall submit an annual report to the department providing a summary of the human  
83 embryonic stem cell research approved during each calendar year pursuant to section 3(b) of this  
84 chapter and a statement representing that such research was reviewed in accordance with this  
85 chapter, if applicable.

86 SECTION 11. In Section 10(n), subsection (2) shall be deleted in its entirety,  
87 and the following language inserted as follows:

88 (2) The department may, after an opportunity for an adjudicatory proceeding conducted  
89 pursuant to chapter 30A, upon determination that an institution conducting research pursuant to  
90 this chapter has violated this subsection undertake the following actions:

91 (i) for the violation of clause (iii) of paragraph (n)(1), revoke or refuse to  
92 renew such certificate of registration or assess upon the holder a civil administrative penalty not  
93 to exceed \$250,000 and may require the holder to submit to additional oversight as a condition or  
94 retention, or future consideration of reinstatement of the certificate of registration;

95 (ii) for a violation of clause (i), (ii), (iv), (vi) or (vii) of paragraph (n)(1),  
96 assess upon the holder a civil administrative penalty not to exceed \$100,000; or

97 (iii) for a first violation of clause (v) of paragraph (n)(1) censure a holder;  
98 and for each subsequent violation of said clause (v) of said paragraph (n)(1), suspend such  
99 certificate of registration until compliance with subsection (i), and impose a civil administrative  
100 penalty, as determined by the department not to exceed \$1,000.“