

SENATE No.

The Commonwealth of Massachusetts

PRESENTED BY:

Cynthia Stone 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 bill:

An Act clarifying chapter 111L - biotechnology.

PETITION OF:

NAME:

Cynthia Stone Creem

DISTRICT/ADDRESS:

First Middlesex and Norfolk

The Commonwealth of Massachusetts

In the Year Two Thousand and Nine

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:

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2 SECTION 1. Paragraph (c) of Section 1 of Chapter 111L of the General Laws as appearing in the 2006
3 Official Edition, is hereby amended by striking in lines 15-16 the words “placental and umbilical cord
4 cells and human adult stem cells”, and inserting at the end of this same paragraph the following
5 sentence:

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7 “Nothing in this chapter shall prohibit research or clinical applications involving human adult
8 stem cells, umbilical cord cells, amniotic fluid cells or placental cells.”

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

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15 ‘ “Donated to research”, when, in the absence of valuable consideration and after
16 fulfillment of the requirements of informed consent, the persons from whose gametes or
17 cells the pre-implantation embryo has originated or will originate gives the pre-
18 implantation embryo, gametes or cells to another person; provided, however, that the
19 recipient shall not transfer the extant or resultant pre-implantation embryo to a uterus or
20 uterine-like environment or nurture the pre-implantation embryo beyond 14 days of
21 development.’
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23 SECTION 3. Said Section 2 is hereby further amended by inserting the following new
24 definitions:

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

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31 ‘ "Reasonable costs", for purposes of reimbursing oocyte donors, may
32 include, but are not limited to, any of the following types of costs if
33 approved by an institutional review board: travel, temporary lodging,
34 childcare, medical care, health insurance (if limited to co-pays and
35 deductibles and the purchase of time-limited accident insurance coverage
36 for complications arising directly from the egg donation process) and
37 actual lost wages, and any other types of such costs as may be approved
38 by such institutional review board.’

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

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

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

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51 “Research and clinical applications involving the derivation and use of
52 human embryonic stem cells from materials donated to research,
53 including, without limitation, pre-implantation embryos, whether created
54 by the method of fertilization or by somatic cell nuclear transfer,
55 parthenogenesis or other asexual means, gametes, somatic cells and
56 parthenotes shall be permitted.”

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

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63 “or ESCRO committee; provided that if such research is approved only by an ESCRO
64 committee, documentation shall be maintained by the ESCRO committee that an
65 institutional review board or another equivalent body determined that any human
66 embryos, cells or gametes to be used in the research were donated to research, as defined

67 in section 2 or in a manner permitted under the laws of the state or foreign country where
68 the donation to research occurred and in a manner otherwise acceptable to the ESCRO.”

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

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

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

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

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

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88 “Notwithstanding section 11A 1/2 of chapter 30A of the General Laws,
89 the council may conduct its meetings by telephone conference or similar
90 communications equipment which allows all persons participating in the
91 meeting to hear each other at the same time. Participation by such means
92 shall constitute presence in person at a meeting. Notice of a meeting held
93 in this manner shall be provided in accordance with the requirements of
94 section 11A 1/2 of chapter 30A of the General Laws, and shall state that
95 members of the public will be afforded a location, as specified in the
96 notice, where they may attend the meeting by conference telephone or
97 similar communications equipment.”

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100 SECTION 9. Section 10(f) of Chapter 111L of the General Laws as appearing in the 2006
101 Official Edition, shall be amended by deleting all language after the words “and (ii)” in line 74
102 and inserting the following language:

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104 “ provides documentation to the department demonstrating that the institution has either
105 an institutional review board or ESCRO committee or both, or provides a copy of a
106 contract between the institution and either a private or public institutional review board or
107 ESCRO committee, as applicable, which shall provide any review required by this
108 chapter. Any institution which submits an application and meets the requirements for a
109 certificate of registration pursuant to this section shall not have the certificate of
110 registration unreasonably withheld. A certificate may be withheld if the department
111 determines that the applicant institution has violated subsection (m).”

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

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

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

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

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

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

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