



General Assembly

January Session, 2015

Raised Bill No. 957

LCO No. 4009



Referred to Committee on COMMERCE

Introduced by:
(CE)

***AN ACT CONCERNING PEER REVIEW PROVISIONS AND THE
DEFINITION OF FINANCIAL ASSISTANCE FOR THE REGENERATIVE
MEDICINE RESEARCH FUND.***

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

1 Section 1. Subsection (a) of section 32-41jj of the general statutes is
2 repealed and the following is substituted in lieu thereof (*Effective*
3 *October 1, 2015*):

4 (a) As used in sections 32-41jj to 32-41mm, inclusive, as amended by
5 this act, and section 4-28e:

6 (1) "Embryonic stem cell research oversight committee" means a
7 committee established in accordance with the National Academies'
8 Guidelines for Human Embryonic Stem Cell Research, as amended
9 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) "Nuclear transfer" means the replacement of the nucleus of a
23 human egg with a nucleus from another human cell.

24 (6) "Eligible institution" means (A) a nonprofit, tax-exempt academic
25 institution of higher education, (B) a hospital that conducts biomedical
26 research, or (C) any entity that conducts biomedical research or
27 regenerative medicine research.

28 (7) "Regenerative medicine" means the process of creating living,
29 functional tissue to repair or replace tissue or organ function lost due
30 to aging, disease, damage or congenital defect. Regenerative medicine
31 includes basic stem cell research.

32 (8) "Financial assistance" means any and all forms of grants,
33 extensions of credit, loans or loan guarantees, equity investments or
34 other forms of financing.

35 Sec. 2. Section 32-41kk of the general statutes is repealed and the
36 following is substituted in lieu thereof (*Effective October 1, 2015*):

37 (a) There is established the "Regenerative Medicine Research Fund",
38 which shall be a separate, nonlapsing account within the General
39 Fund. The fund may contain any moneys required or permitted by law
40 to be deposited in the fund and any funds received from any public or
41 private contributions, gifts, grants, donations, bequests or devises to

42 the fund. The chief executive officer of Connecticut Innovations,
43 Incorporated, (1) shall [make grants-in-aid] award financial assistance
44 from the fund in accordance with the provisions of subsection (b) of
45 this section, and (2) may enter into agreements with other entities,
46 including, but not limited to, the government of any state or foreign
47 country for the purpose of advancing research collaboration
48 opportunities for recipients of [grants-in-aid] financial assistance under
49 this section.

50 (b) The Regenerative Medicine Research Advisory Committee
51 established pursuant to section 32-41ll, as amended by this act, shall
52 develop an application for [grants-in-aid] financial assistance under
53 this section for the purpose of conducting regenerative medicine
54 research and may receive applications from eligible institutions for
55 such [grants-in-aid] financial assistance. The Regenerative Medicine
56 Research Advisory Committee shall require any applicant for [a grant-
57 in-aid] financial assistance under this section to conduct regenerative
58 medicine research to submit (1) a complete description of the
59 applicant's organization, (2) the applicant's plans for regenerative
60 medicine research and proposed funding for such research from
61 sources other than the state, and (3) proposed arrangements
62 concerning financial benefits to the state as a result of any patent,
63 royalty payment or similar rights developing from any proposed
64 research made possible by the awarding of such [grant-in-aid]
65 financial assistance. The Regenerative Medicine Research Advisory
66 Committee shall direct the chief executive officer of Connecticut
67 Innovations, Incorporated, with respect to the awarding of such
68 [grants-in-aid] financial assistance after considering recommendations
69 from [the Regenerative Medicine Research Peer Review Committee
70 established pursuant to section 32-41mm] the peer review panel
71 selected by said advisory committee pursuant to section 32-41mm, as
72 amended by this act.

73 (c) Commencing with the fiscal year ending June 30, 2006, and for
74 each of the thirteen consecutive fiscal years thereafter, until the fiscal

75 year ending June 30, 2019, not less than ten million dollars shall be
76 available from the Regenerative Medicine Research Fund for [grants-
77 in-aid] financial assistance to eligible institutions for the purpose of
78 conducting regenerative medicine research. Any balance of such
79 amount not used for such [grants-in-aid] financial assistance during a
80 fiscal year shall be carried forward for the fiscal year next succeeding
81 for such [grants-in-aid] financial assistance.

82 Sec. 3. Section 32-411l of the general statutes is repealed and the
83 following is substituted in lieu thereof (*Effective October 1, 2015*):

84 (a) (1) There is established a Regenerative Medicine Research
85 Advisory Committee. The committee shall consist of the
86 Commissioner of Public Health, or the commissioner's designee, the
87 chief executive officer of Connecticut Innovations, Incorporated, or the
88 chief executive officer's designee, and eight members who shall be
89 appointed as follows: Two by the Governor, one of whom shall have
90 background and experience in stem cell or regenerative medicine
91 research and one of whom shall have background and experience in
92 business or financial investments; one each by the president pro
93 tempore of the Senate and the speaker of the House of Representatives,
94 who shall have background and experience in private sector
95 regenerative medicine research and development; one each by the
96 majority leaders of the Senate and House of Representatives, who shall
97 be academic researchers specializing in regenerative medicine
98 research; one by the minority leader of the Senate, who shall have
99 background and experience in either private or public sector
100 regenerative medicine research and development or related research
101 fields, including, but not limited to, embryology, genetics or cellular
102 biology; and one by the minority leader of the House of
103 Representatives, who shall have background and experience in the
104 field of bioethics. Members shall serve for a term of four years
105 commencing on October first, except that members first appointed by
106 the Governor and the majority leaders of the Senate and House of
107 Representatives shall serve for a term of two years. No member may

108 serve for more than two consecutive four-year terms. All initial
109 appointments to the committee shall be made by October 1, 2005. Any
110 vacancy shall be filled by the appointing authority.

111 (2) The Regenerative Medicine Research Advisory Committee shall
112 include eight additional members who shall be appointed as follows:
113 Two by the Governor, who shall have backgrounds and experience in
114 business or financial investments; one each by the president pro
115 tempore of the Senate and the speaker of the House of Representatives,
116 who shall have background and experience in private sector
117 regenerative medicine research and development; one each by the
118 majority leaders of the Senate and House of Representatives, who shall
119 be academic researchers specializing in regenerative medicine
120 research; one by the minority leader of the Senate, who shall have
121 background and experience in either private or public sector
122 regenerative medicine research and development or related research
123 fields, including, but not limited to, embryology, genetics or cellular
124 biology; and one by the minority leader of the House of
125 Representatives, who shall have background and experience in
126 business, law or ethics. Members shall serve for a term of four years,
127 except that (A) members first appointed by the Governor and the
128 majority leaders of the Senate and House of Representatives pursuant
129 to this subdivision shall serve for a term of two years and three
130 months, and (B) members first appointed by the remaining appointing
131 authorities shall serve for a term of four years and three months. No
132 member appointed pursuant to this subdivision may serve for more
133 than two consecutive four-year terms. All initial appointments to the
134 committee pursuant to this subdivision shall be made by July 1, 2006.
135 Any vacancy shall be filled by the appointing authority.

136 (b) The chief executive officer of Connecticut Innovations,
137 Incorporated, or the chief executive officer's designee, shall serve as
138 chairperson of the Regenerative Medicine Research Advisory
139 Committee.

140 (c) All members appointed to said advisory committee shall work to
141 advance regenerative medicine research. Any member who fails to
142 attend three consecutive meetings or who fails to attend fifty per cent
143 of all meetings held during any calendar year shall be deemed to have
144 resigned from said advisory committee.

145 (d) Notwithstanding the provisions of any other law, it shall not
146 constitute a conflict of interest for a trustee, director, partner, officer,
147 stockholder, proprietor, counsel or employee of any eligible institution,
148 or for any other individual with a financial interest in any eligible
149 institution, to serve as a member of said advisory committee. All
150 members shall be deemed public officials and shall adhere to the code
151 of ethics for public officials set forth in chapter 10. Members may
152 participate in the affairs of said advisory committee with respect to the
153 review or consideration of [grant-in-aid] applications for financial
154 assistance, including the approval or disapproval of such applications,
155 except that no member shall participate in the affairs of said advisory
156 committee with respect to the review or consideration of any [grant-in-
157 aid] application for financial assistance filed by such member or by any
158 eligible institution in which such member has a financial interest, or
159 with whom such member engages in any business, employment,
160 transaction or professional activity.

161 (e) The Regenerative Medicine Research Advisory Committee shall
162 (1) develop, in consultation with Connecticut Innovations,
163 Incorporated, a donated funds program to encourage the development
164 of funds other than state appropriations for regenerative medicine
165 research in the state, (2) examine and identify specific ways to improve
166 and promote for-profit and not-for-profit regenerative medicine
167 research and research in related areas in the state, including, but not
168 limited to, identifying both public and private funding sources for
169 such research, maintaining existing regenerative medicine-related
170 businesses, recruiting new regenerative medicine-related businesses to
171 the state and recruiting scientists and researchers in such field to the
172 state, (3) administer a regenerative medicine research [grant] assistance

173 program that shall provide [grants-in-aid] financial assistance to
174 eligible institutions for the advancement of regenerative medicine
175 research in the state pursuant to section 32-41kk, as amended by this
176 act, (4) monitor the regenerative medicine research conducted by
177 eligible institutions that receive such [grants-in-aid] financial
178 assistance, and (5) prepare a comprehensive strategic plan for the
179 Regenerative Medicine Research Fund, established pursuant to section
180 32-41kk, as amended by this act, and [grants-in-aid made] financial
181 assistance awarded from said fund that shall include, but need not be
182 limited to, identification of specific methods or strategies to (A)
183 achieve the scientific and economic development objective of said
184 fund, (B) build innovation capacity, and (C) sustain investments of
185 moneys received by said fund.

186 (f) Connecticut Innovations, Incorporated, shall serve as
187 administrator of the Regenerative Medicine Research Fund and shall,
188 in consultation with the Regenerative Medicine Research Advisory
189 Committee: (1) Develop the application for the [grants-in-aid] financial
190 assistance authorized under subsection (b) of section 32-41kk, as
191 amended by this act; (2) review such applications; (3) review
192 recommendations of the Regenerative Medicine Research Advisory
193 Committee, established pursuant to section 32-41mm, as amended by
194 this act; (4) prepare and execute any assistance agreements or other
195 agreements in connection with the awarding of such [grants-in-aid]
196 financial assistance; (5) develop performance metrics and systems to
197 collect data from recipients of such [grants-in-aid] financial assistance;
198 (6) collect information from such recipients concerning each recipient's
199 employment statistics, business accomplishments and performance
200 outcomes, peer review articles and papers published, partnerships and
201 collaborations with other entities, licenses, patents and invention
202 disclosures, scientific progress as it relates to the commercialization of
203 intellectual property funded by such [grants-in-aid] financial
204 assistance, efforts to commercialize such intellectual property, and
205 other funds received for research; and (7) performing such other

206 administrative duties as the Regenerative Medicine Research Advisory
207 Committee deems necessary.

208 Sec. 4. Section 32-41mm of the general statutes is repealed and the
209 following is substituted in lieu thereof (*Effective October 1, 2015*):

210 [(a) (1) There is established a Regenerative Medicine Research Peer
211 Review Committee. Said peer review committee shall consist of five
212 members.

213 (2) On and before September 30, 2014, all members appointed by the
214 Commissioner of Public Health to the committee shall (A) have
215 demonstrated knowledge and understanding of the ethical and
216 medical implications of regenerative medicine research or related
217 research fields, including, but not limited to, embryology, genetics or
218 cellular biology, (B) have practical research experience in regenerative
219 medicine research or related research fields, including, but not limited
220 to, embryology, genetics or cellular biology, and (C) work to advance
221 regenerative medicine research. Members shall serve for a term of four
222 years commencing on October first, except that three members first
223 appointed by the Commissioner of Public Health shall serve for a term
224 of two years. No member may serve for more than two consecutive
225 four-year terms and no member may serve concurrently on the
226 Regenerative Medicine Research Advisory Committee established
227 pursuant to section 32-41ll. All initial appointments to said peer review
228 committee shall be made by October 1, 2005. Any member who fails to
229 attend three consecutive meetings or who fails to attend fifty per cent
230 of all meetings held during any calendar year shall be deemed to have
231 resigned from said peer review committee.

232 (3) On and after October 1, 2014, each member appointed by the
233 Commissioner of Public Health pursuant to subdivision (2) of this
234 subsection may serve to the conclusion of his or her current term at
235 which time members shall be appointed by the chief executive officer
236 of Connecticut Innovations, Incorporated, as follows: Members

237 appointed to said peer review committee shall: (A) Have demonstrated
238 knowledge and understanding of the ethical and medical implications
239 of regenerative medicine research or research in a related field,
240 including, but not limited to, embryology, genetics or cellular biology;
241 (B) have practical research experience in regenerative medicine
242 research or research in a related field, including, but not limited to,
243 embryology, genetics or cellular biology; and (C) work to advance
244 regenerative medicine research. Members shall serve for a term of four
245 years, except that three members first appointed by the chief executive
246 officer of Connecticut Innovations, Incorporated, shall serve for a term
247 of two years. No member may serve for more than two consecutive
248 four-year terms and no member may serve concurrently on the
249 Regenerative Medicine Research Advisory Committee established
250 pursuant to section 32-41*ll*. Any member who fails to attend three
251 consecutive meetings or who fails to attend fifty per cent of all
252 meetings held during any calendar year shall be deemed to have
253 resigned from said peer review committee.

254 (b) All members shall be deemed public officials and shall adhere to
255 the code of ethics for public officials set forth in chapter 10. No
256 member shall participate in the affairs of the committee with respect to
257 the review or consideration of any grant-in-aid application filed by
258 such member or by any eligible institution in which such member has
259 a financial interest, or with which such member engages in any
260 business, employment, transaction or professional activity.]

261 (a) The Regenerative Medicine Research Advisory Committee
262 established pursuant to section 32-41*ll*, as amended by this act, shall
263 select an independent panel of professional peer reviewers who shall:
264 (1) Have demonstrated knowledge and understanding of the ethical
265 and medical implications of regenerative medicine research or related
266 research fields, including, but not limited to, embryology, genetics or
267 cellular biology, (2) have practical research experience in regenerative
268 medicine research or related research fields, including, but not limited
269 to, embryology, genetics or cellular biology, and (3) work to advance

270 regenerative medicine research.

271 [(c)] (b) Prior to the awarding of any [grants-in-aid] financial
272 assistance for regenerative medicine research pursuant to section 32-
273 41kk, as amended by this act, [the Regenerative Medicine Research
274 Peer Review Committee] said peer reviewers shall review all
275 applications submitted by eligible institutions for such [grants-in-aid]
276 financial assistance and make recommendations to the Regenerative
277 Medicine Research Advisory Committee established pursuant to
278 section 32-41ll, as amended by this act, with respect to the ethical and
279 scientific merit of each application.

280 [(d)] (c) [Members of the Regenerative Medicine Research Peer
281 Review Committee] Said peer reviewers may receive compensation
282 from Connecticut Innovations, Incorporated, for reviewing grant-in-
283 aid applications submitted by eligible institutions. The rate of
284 compensation shall be established by the board of directors of
285 Connecticut Innovations, Incorporated.

286 [(e)] (d) The Regenerative Medicine Research [Peer Review
287 Committee] Advisory Board, in consultation with said peer reviewers,
288 shall establish guidelines for the rating and scoring of such
289 applications.

290 [(f) All members of said peer review committee] (e) All said peer
291 reviewers shall become and remain fully cognizant of the National
292 Academies' Guidelines for Human Embryonic Stem Cell Research, as
293 amended from time to time, and shall utilize said guidelines to
294 evaluate each grant-in-aid application.

This act shall take effect as follows and shall amend the following sections:		
Section 1	<i>October 1, 2015</i>	32-41jj(a)
Sec. 2	<i>October 1, 2015</i>	32-41kk
Sec. 3	<i>October 1, 2015</i>	32-41ll

Sec. 4	October 1, 2015	32-41mm
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Statement of Purpose:

To allow types of financial assistance in addition to grants to be awarded from the Regenerative Medicine Research Fund and to replace the Regenerative Medicine Research Peer Review Committee with an independent panel of professional peer reviewers chosen by the Regenerative Medicine Research Advisory Committee.

[Proposed deletions are enclosed in brackets. Proposed additions are indicated by underline, except that when the entire text of a bill or resolution or a section of a bill or resolution is new, it is not underlined.]