

1 A bill to be entitled

2 An act relating to biomedical research; amending s.
3 20.435, F.S.; revising uses for funds credited to the
4 Biomedical Research Trust Fund; amending s. 381.86, F.S.;
5 providing that the Institutional Review Board within the
6 Department of Health shall not review certain research
7 within the jurisdiction of the Stem Cell Research Advisory
8 Council; creating s. 381.99, F.S.; creating the Florida
9 Better Quality of Life and Biomedical Research Act;
10 providing a short title; providing definitions; creating
11 the Stem Cell Research Advisory Council; providing for
12 appointment, terms, and duties of members; authorizing
13 reimbursement for per diem and travel expenses; requiring
14 a report; requiring the Department of Health to provide
15 administrative support; creating the Biomedical Ethics
16 Advisory Council to regulate research procedures and
17 enforce ethical guidelines; providing for appointment,
18 terms, and duties of members; authorizing reimbursement
19 for per diem and travel expenses; providing duties of the
20 council; providing for a grants-in-aid program for the
21 purpose of conducting embryonic, amniotic, or human adult
22 stem cell research; providing that grants-in-aid shall be
23 provided through funds in the Biomedical Research Trust
24 Fund; restricting the use of such funds for research on
25 certain stem cells; providing requirements with respect to
26 the disposition of human embryos following infertility
27 treatment; requiring the Department of Health to develop
28 and maintain on its Internet website a consent form for

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29 the donation of certain embryos; prohibiting purchase or
30 sale of embryonic fetal tissue for research purposes;
31 prohibiting certain acts relating to human reproductive
32 cloning; providing penalties; providing a continuing
33 appropriation; providing an effective date.

34
35 WHEREAS, an estimated 130 million Americans suffer from
36 acute, chronic, and degenerative diseases and there is enormous
37 potential for lifesaving treatment and therapy as a result of
38 recent advances in biomedical research, and

39 WHEREAS, Florida is unique among all states because of the
40 size of the projected net population increase within the next 20
41 years which raises significant health care concerns as a new
42 generation of retirees moves to Florida, resulting in a
43 corresponding rise in the number of persons suffering from
44 illnesses such as cancer, heart disease, Alzheimer's Disease,
45 Parkinson's Disease, cerebral palsy, juvenile diabetes,
46 atherosclerosis, Amyotrophic Lateral Sclerosis, AIDS, spinal
47 cord injuries, severe burns, osteoporosis, osteoarthritis,
48 cystic fibrosis, muscular dystrophy, multiple sclerosis, macular
49 degeneration, diabetic retinopathy, retinitis pigmentosa,
50 cirrhosis of the liver, motor neuron disease, brain trauma,
51 stroke, sickle cell anemia, and intestinal diseases, and

52 WHEREAS, in order to maintain a high quality of life for
53 all Floridians, research into stem cell regenerative therapies
54 and treatment should be supported to give hope and relief to the
55 millions of citizens who suffer from degenerative and crippling
56 diseases, and

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57 WHEREAS, to reduce the burden on the health care
58 infrastructure, the state must shift its health care objectives
59 from costly long-term maintenance toward prevention and cures,
60 and

61 WHEREAS, to bolster and advance Florida's burgeoning
62 biotechnology industry, the state should provide funds and
63 incentives for private research companies to work in the state,
64 and

65 WHEREAS, the state should advance the goal of scientific
66 and academic discourse in its universities and help bring its
67 public and private universities to the forefront in biomedical
68 research and technology, and

69 WHEREAS, it will benefit the economy of the state to create
70 a wide array of new projects and high-paying jobs relating to
71 biomedical research, and

72 WHEREAS, it will benefit the state to foster cooperation
73 between the state's universities and private sector research in
74 terms of jobs, resources, and academic discourse relating to
75 biomedical research, and

76 WHEREAS, the public funds provided under the Florida Better
77 Quality of Life and Biomedical Research Act are intended to spur
78 innovation and development in Florida's biomedical technology
79 sector, which will be used to treat debilitating chronic
80 diseases, NOW, THEREFORE,

81

82 Be It Enacted by the Legislature of the State of Florida:

83

84 Section 1. Paragraph (h) of subsection (1) of section

85 20.435, Florida Statutes, is amended to read:

86 20.435 Department of Health; trust funds.--

87 (1) The following trust funds are hereby created, to be
88 administered by the Department of Health:

89 (h) Biomedical Research Trust Fund.

90 1. Funds to be credited to the trust fund shall consist of
91 funds deposited pursuant to ss. ~~215.5601, 288.955, and~~
92 381.99, and any other funds appropriated by the Legislature.
93 Funds shall be used for the purposes of the James and Esther
94 King Biomedical Research Program, ~~and~~ the William G. "Bill"
95 Bankhead, Jr., and David Coley Cancer Research Program, and the
96 Florida Better Quality of Life and Biomedical Research Act as
97 specified in ss. 215.5602, 288.955, ~~and 381.922,~~ and 381.99. The
98 trust fund is exempt from the service charges imposed by s.
99 215.20.

100 2. Notwithstanding the provisions of s. 216.301 and
101 pursuant to s. 216.351, any balance in the trust fund at the end
102 of any fiscal year shall remain in the trust fund at the end of
103 the year and shall be available for carrying out the purposes of
104 the trust fund. The department may invest these funds
105 independently through the Chief Financial Officer or may
106 negotiate a trust agreement with the State Board of
107 Administration for the investment management of any balance in
108 the trust fund.

109 3. Notwithstanding s. 216.301 and pursuant to s. 216.351,
110 any balance of any appropriation from the Biomedical Research
111 Trust Fund which is not disbursed but which is obligated
112 pursuant to contract or committed to be expended may be carried

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113 forward for up to 3 years following the effective date of the
 114 original appropriation.

115 4. The trust fund shall, unless terminated sooner, be
 116 terminated on July 1, 2008.

117 Section 2. Subsection (2) of section 381.86, Florida
 118 Statutes, is amended to read:

119 381.86 Institutional Review Board.--

120 (2) Consistent with federal requirements, the Secretary of
 121 Health shall determine and appoint the membership of the board
 122 and designate its chair, except that a separate Stem Cell
 123 Research Advisory Council shall be appointed pursuant to s.
 124 381.99 for the sole purpose of reviewing research funded under
 125 that section.

126 Section 3. Section 381.99, Florida Statutes, is created to
 127 read:

128 381.99 Florida Better Quality of Life and Biomedical
 129 Research Act.--

130 (1) SHORT TITLE.--This section may be cited as the
 131 "Florida Better Quality of Life and Biomedical Research Act."

132 (2) DEFINITIONS.--As used in this section, the term:

133 (a) "Adult stem cell" means an undifferentiated cell found
 134 among differentiated cells in a tissue or an organ that can
 135 renew itself and can differentiate to yield the major
 136 specialized cell types of the tissue or organ.

137 (b) "Amniotic stem cell" means a cell extracted from human
 138 amniotic fluid or a placenta.

139 (c) "Embryonic stem cell" means a cell obtained from the
 140 undifferentiated inner mass of an early stage embryo.

141 (d) "Human reproductive cloning" means the practice of
 142 creating or attempting to create a human being by transferring
 143 the nucleus from a human cell into an egg cell from which the
 144 nucleus has been removed for the purpose of implanting the
 145 resulting product in a uterus or a substitute for a uterus to
 146 initiate a pregnancy.

147 (e) "In vitro fertilization" means a technique by which
 148 oocytes are fertilized by sperm outside of a woman's body
 149 resulting in organisms that are not genetically identical to any
 150 one existing human.

151 (f) "Stem cell" means an undifferentiated cell that
 152 retains the potential to differentiate into some or all other
 153 cell types.

154 (3) STEM CELL RESEARCH ADVISORY COUNCIL.--There is created
 155 the Stem Cell Research Advisory Council.

156 (a) The advisory council shall consist of the Secretary of
 157 Health or his or her designee, who shall act as chair, and six
 158 additional members, who shall be appointed as follows:

159 1. Two persons appointed by the Governor, one of whom
 160 shall be an academic researcher in the field of stem cell
 161 research and one of whom shall have a background in bioethics.

162 2. One person appointed by the President of the Senate,
 163 who shall have a background in private sector stem cell funding
 164 and development and public sector biomedical research and
 165 funding.

166 3. One person appointed by the Speaker of the House of
 167 Representatives, who shall have a background in private sector

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168 stem cell funding and development and public sector biomedical
169 research and funding.

170 4. One person appointed by the Minority Leader of the
171 Senate, who shall have a background and experience in either
172 public sector or private sector stem cell research and
173 development.

174 5. One person appointed by the Minority Leader of the
175 House of Representatives, who shall have a background and
176 experience in business and financial investments.

177
178 Each member shall serve a term of 2 years commencing on October
179 1, 2007. No member shall serve for more than two consecutive 2-
180 year terms; however, for the purpose of providing staggered
181 terms, of the initial appointments, three members shall be
182 appointed to a 1-year term and three members shall be appointed
183 to a 2-year term. No member shall serve for more than two
184 consecutive terms. Any vacancy on the council shall be filled in
185 the same manner as the original appointment. All initial
186 appointments must be made by October 1, 2007. The first meeting
187 shall take place no later than November 1, 2007. All meetings
188 are subject to the call of the chair. Members shall meet at
189 least twice a year or as often as necessary to discharge their
190 duties but shall have no more than four meetings during any 12-
191 month period. Members shall serve without compensation but may
192 be reimbursed for per diem and travel expenses in accordance
193 with s. 112.061.

194 (b) The advisory council shall:

195 1. Develop a donated funds program for recommendation to
196 the Secretary of Health to encourage the development of funds
197 other than state appropriations for embryonic, amniotic, and
198 human adult stem cell research in the state.

199 2. Examine and identify specific ways to improve and
200 promote for-profit and not-for-profit embryonic, amniotic, and
201 human adult stem cell and related research in the state,
202 including, but not limited to, identifying both public and
203 private funding sources for such research, maintaining existing
204 embryonic, amniotic, and human adult stem cell related
205 businesses, recruiting new embryonic, amniotic, and human adult
206 stem cell related businesses to the state, and recruiting
207 scientists and researchers in such fields to the state and state
208 universities.

209 3. Develop a biomedical research grant program for
210 recommendation to the Secretary of Health, which shall provide
211 grants-in-aid to eligible institutions for the advancement of
212 embryonic, amniotic, or human adult stem cell research.

213 4. Develop, no later than December 1, 2007, an application
214 for grants-in-aid under this section for recommendation to the
215 Secretary of Health for the purpose of conducting embryonic,
216 amniotic, or human adult stem cell research.

217 5. Review applications from eligible institutions for
218 grants-in-aid on and after December 1, 2007, and provide to the
219 Secretary of Health recommended grant awards.

220 6. Review the stem cell research conducted by eligible
221 institutions that receive such grants-in-aid.

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222 (c) The advisory council shall submit an annual progress
223 report on the status of biomedical research in the state to the
224 Florida Center for Universal Research to Eradicate Disease and
225 to the Governor, the Secretary of Health, the President of the
226 Senate, and the Speaker of the House of Representatives by June
227 30. The report must include:

228 1. The amount of grants-in-aid awarded to eligible
229 institutions from the Biomedical Research Trust Fund.

230 2. The names of the recipients of such grants-in-aid.

231 3. The current status and progress of stem cell research
232 in the state.

233 4. A list of research projects supported by grants-in-aid
234 awarded under the program.

235 5. A list of publications in peer-reviewed journals
236 involving research supported by grants-in-aid awarded under the
237 program.

238 6. The total amount of biomedical research funding
239 currently flowing into the state.

240 7. New grants for biomedical research that were funded
241 based on research supported by grants-in-aid awarded under the
242 program.

243 8. All other materials the council deems advisable to
244 include.

245 (d) Advisory council members shall disclose any conflict
246 of interest or potential conflict of interest to the Secretary
247 of Health.

248 (e) The Department of Health shall provide administrative
249 staff to assist the advisory council in developing the

250 application for the grants-in-aid, reviewing the applications,
 251 preparing the written consent form described in paragraph
 252 (6) (b), and performing other administrative functions as the
 253 advisory council requires.

254 (4) BIOMEDICAL ETHICS ADVISORY COUNCIL.--There is created
 255 within the Department of Health the Biomedical Ethics Advisory
 256 Council, which shall review the research conducted under s.
 257 381.99.

258 (a) The advisory council shall consist of the Secretary of
 259 Health or his or her designee, who shall act as chair, and six
 260 additional members, who shall be appointed as follows:

- 261 1. Two persons appointed by the Governor.
- 262 2. One person appointed by the President of the Senate.
- 263 3. One person appointed by the Speaker of the House of
 264 Representatives.
- 265 4. One person appointed by the Minority Leader of the
 266 Senate.
- 267 5. One person appointed by the Minority Leader of the
 268 House of Representatives.

269

270 All members must demonstrate knowledge and understanding of the
 271 ethical, medical, and scientific implications of embryonic,
 272 amniotic, and adult stem cell research and should also
 273 demonstrate knowledge of related fields, including, but not
 274 limited to, genetics, cellular biology, and embryology. Each
 275 member shall serve a term of 4 years commencing on October 1,
 276 2007; however, for the purpose of providing staggered terms, of
 277 the initial appointments, three members shall be appointed to a

278 2-year term and three members shall be appointed to a 4-year
 279 term. No member shall serve for more than two consecutive terms.
 280 Any vacancy on the council shall be filled in the same manner as
 281 the original appointment. All initial appointments must be made
 282 by October 1, 2007. The first meeting shall take place no later
 283 than November 1, 2007. All meetings are subject to the call of
 284 the chair. Members shall meet at least twice a year or as often
 285 as necessary to discharge their duties but shall have no more
 286 than one meeting per month during any 12-month period. Members
 287 shall serve without compensation but may be reimbursed for per
 288 diem and travel expenses in accordance with s. 112.061.

289 (b) The council shall review all embryonic, amniotic, or
 290 human adult stem cell research that is funded or supported in
 291 any manner through the Biomedical Research Trust Fund to ensure
 292 the adherence to ethical and safety guidelines and procedures as
 293 laid out by federal ethical standards established by the United
 294 States Department of Health and Human Services.

295 (5) BIOMEDICAL RESEARCH TRUST FUND AND GRANTS-IN-AID.--

296 (a) The Secretary of Health shall make grants-in-aid from
 297 the Biomedical Research Trust Fund in accordance with the
 298 provisions of this section.

299 (b) The Department of Health shall require any applicant
 300 for a grant-in-aid under this section, for the purpose of
 301 conducting stem cell research, to submit a complete description
 302 of the applicant's organization, the applicant's plans for stem
 303 cell research, the applicant's proposed funding for such
 304 research from sources other than the state, and the applicant's
 305 proposed arrangements concerning financial benefits to the state

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306 as a result of any patent, royalty payment, or similar right
307 resulting from any stem cell research made possible by the
308 awarding of the grant-in-aid. The Stem Cell Research Advisory
309 Council shall provide recommendations to the Secretary of Health
310 with respect to awarding such grants-in-aid after considering
311 the recommendations of the Biomedical Ethics Advisory Council.

312 (c) Beginning with the 2007-2008 fiscal year, and for 10
313 consecutive years thereafter, not less than \$20 million shall be
314 made available from the Biomedical Research Trust Fund within
315 the Department of Health for grants-in-aid to eligible
316 institutions for the purpose of conducting embryonic, amniotic,
317 or human adult stem cell research pursuant to this section. Up
318 to 15 percent of the funds may be used for administrative costs.
319 Any unexpended funds not used for grants-in-aid during the
320 current fiscal year shall be carried forward for the following
321 fiscal year to fund the grants-in-aid.

322 (6) USE OF FUNDS; REQUIREMENTS AND RESTRICTIONS REGARDING
323 DISPOSITION OF HUMAN EMBRYOS FOLLOWING INFERTILITY TREATMENT.--

324 (a) Funds provided under this section may only be used for
325 research involving:

326 1. Human adult stem cells, including, but not limited to,
327 adult stem cells derived from umbilical cord blood and bone
328 marrow.

329 2. Human embryonic stem cells taken from donated leftover
330 embryos from in vitro fertilization treatments that would
331 otherwise be thrown away or destroyed.

332 3. Amniotic stem cells extracted from human amniotic fluid
333 or placentas, which are otherwise discarded after birth.

334 (b) A physician or other health care provider treating a
335 patient for infertility shall provide the patient with timely,
336 relevant, and appropriate information sufficient to allow the
337 person to make an informed and voluntary choice regarding the
338 disposition of any human embryos that remain following
339 infertility treatment. The person to whom the information is
340 provided:

341 1. Shall be presented with the option of storing any
342 unused embryos remaining after receiving in vitro fertilization,
343 donating the remaining embryos to another person, donating the
344 remaining embryos for research purposes, or selecting other
345 means of disposition of the remaining embryos.

346 2. Who elects to donate, for research purposes, any
347 embryos remaining after receiving infertility treatment shall
348 provide written consent for that donation on a consent form
349 provided by the Department of Health and made available to the
350 public on the department's Internet website.

351 3. May not knowingly, for material or financial gain,
352 purchase, sell, or otherwise transfer or obtain, or promote the
353 sale or transfer of, embryonic fetal tissue for research
354 purposes pursuant to this section. Embryonic, amniotic, and
355 adult stem cell material may only be donated for research
356 purposes with the informed consent of the donor. A person who
357 violates any provision of this subparagraph commits a felony of
358 the second degree, punishable as provided in s. 775.082, s.
359 775.083, or s. 775.084.

360 (7) HUMAN REPRODUCTIVE CLONING; PROHIBITION; PENALTIES.--

361 (a) It is unlawful for any person to knowingly:

- 362 1. Perform or attempt to perform human reproductive
 363 cloning;
 364 2. Participate or assist in an attempt to perform human
 365 reproductive cloning; or
 366 3. Ship or receive for any purpose an embryo produced by
 367 human reproductive cloning or any product derived from such
 368 embryo.

369 (b) A person who violates any provision of paragraph (a)
 370 commits a felony of the second degree, punishable as provided in
 371 s. 775.082, s. 775.083, or s. 775.084.

372 (8) CONTINUING APPROPRIATION.--Beginning in fiscal year
 373 2007-2008, the sum of \$20 million is appropriated annually from
 374 recurring funds in the General Revenue Fund to the Biomedical
 375 Research Trust Fund within the Department of Health for the
 376 purposes of carrying out the provisions of this section. The
 377 amount of funds appropriated shall not exceed \$200 million for
 378 the 10-year period beginning in fiscal year 2007-2008 and ending
 379 in fiscal year 2016-2017.

380 Section 4. This act shall take effect July 1, 2007.