

1 A bill to be entitled
 2 An act relating to stem cell research; creating s. 381.99,
 3 F.S.; providing a short title; providing definitions;
 4 creating the Stem Cell Research Advisory Council and
 5 Biomedical Ethics Advisory Council within the Department
 6 of Health; providing for membership and terms; providing
 7 duties and responsibilities; requiring the Secretary of
 8 Health to make grants-in-aid from the Biomedical Research
 9 Trust Fund for stem cell research; providing requirements
 10 relating to applications for and awards of such grants-in-
 11 aid; providing specifications for moneys to be made
 12 available from the trust fund for stem cell research
 13 grants-in-aid; providing restrictions and requirements for
 14 uses of funds from such grants-in-aid; providing
 15 prohibitions relating to human cloning; providing for
 16 penalties; providing an appropriation; amending s. 20.435,
 17 F.S.; revising references; amending s. 381.86, F.S.;
 18 providing an exception to the Institutional Review Board
 19 for the Stem Cell Research Advisory Council and Biomedical
 20 Ethics Advisory Council; providing an effective date.

21
 22 Be It Enacted by the Legislature of the State of Florida:

23
 24 Section 1. Section 381.99, Florida Statutes, is created to
 25 read:

26 381.99 Florida Hope Offered through Principled, Ethically
 27 Sound Stem Cell Research Act.--

28 (1) SHORT TITLE.--This section may be cited as the

29 "Florida Hope Offered through Principled, Ethically Sound Stem
30 Cell Research Act."

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

32 (a) "Adult stem cell" means a cell found within
33 differentiated tissue or an organ that can renew itself and give
34 rise to the major cell types of the tissue or organ. This
35 includes cells from the fetal to adult stages of development.

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

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

40 (d) "Human cloning" means human asexual reproduction,
41 accomplished by introducing nuclear material from one or more
42 human somatic cells into a fertilized or unfertilized oocyte the
43 nuclear material of which has been removed or inactivated so as
44 to produce a living organism at any stage of development that is
45 genetically virtually identical to an existing or previously
46 existing human organism.

47 (e) "Stem cell" means a cell that retains the potential to
48 generate some or all other cell types.

49 (3) STEM CELL RESEARCH ADVISORY COUNCIL.--There is created
50 the Stem Cell Research Advisory Council within the Department of
51 Health.

52 (a)1. The advisory council shall consist of the Secretary
53 of Health or his or her designee, who shall act as chair, and
54 six additional members, who shall be appointed as follows:

55 a. Two persons appointed by the Governor, one of whom
56 shall be an academic researcher in the field of stem cell

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57 research and one of whom shall have a background in bioethics.

58 b. One person appointed by the President of the Senate,
59 who shall have a background in private-sector stem cell funding
60 and development or public-sector biomedical research and
61 funding.

62 c. One person appointed by the Speaker of the House of
63 Representatives, who shall have a background in private-sector
64 stem cell funding and development or public-sector biomedical
65 research and funding.

66 d. One person appointed by the President of the Senate,
67 who shall have a background and experience in either public-
68 sector or private-sector stem cell research and development.

69 e. One person appointed by the Speaker of the House of
70 Representatives, who shall be an executive of a biotech company,
71 or his or her designee.

72 2. Each member shall serve a term of 2 years commencing on
73 October 1, 2007. No member shall serve for more than two
74 consecutive 2-year terms; however, for the purpose of providing
75 staggered terms, of the initial appointments, three members
76 shall be appointed to a 1-year term and three members shall be
77 appointed to a 2-year term. Any vacancy on the advisory council
78 shall be filled in the same manner as the original appointment.
79 All initial appointments shall be made by October 1, 2007. The
80 first meeting shall take place no later than November 1, 2007.
81 All meetings are subject to the call of the chair. Members shall
82 meet at least twice a year or as often as necessary to discharge
83 their duties but shall have no more than four meetings during
84 any 12-month period. Members shall serve without compensation

85 but may
86 be reimbursed for per diem and travel expenses in accordance
87 with s. 112.061.

88 (b) The advisory council shall:

89 1. Develop a donated funds program for recommendation to
90 the Secretary of Health to encourage the development of funds
91 other than state appropriations for human adult stem cell
92 research in the state.

93 2. Examine and identify specific ways to improve and
94 promote for-profit and not-for-profit human adult stem cell and
95 related research in the state, including, but not limited to,
96 identifying both public and private funding sources for such
97 research, maintaining existing human adult stem cell-related
98 businesses, recruiting new human adult stem cell-related
99 businesses to the state, and recruiting scientists and
100 researchers in such fields to the state and state universities.

101 3. Develop a biomedical research grant program for
102 recommendation to the Secretary of Health that shall provide
103 grants-in-aid to eligible state institutions for the advancement
104 of human adult stem cell research.

105 4. Develop, no later than December 1, 2007, an application
106 for grants-in-aid under this section for recommendation to the
107 Secretary of Health for the purpose of conducting human adult
108 stem cell research.

109 5. Review applications from eligible institutions for
110 grants-in-aid on and after December 1, 2007, and provide to the
111 Secretary of Health recommendations for grant awards.

112 6. Review the stem cell research conducted by eligible

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113 institutions that receive such grants-in-aid.

114 (c) The advisory council shall submit an annual progress
115 report on the status of biomedical research in the state to the
116 Florida Center for Universal Research to Eradicate Disease and
117 to the Governor, the Secretary of Health, the President of the
118 Senate, and the Speaker of the House of Representatives by June
119 30. The report must include:

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

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

123 3. The current status and progress of stem cell research
124 in the state.

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

127 5. A list of publications in peer-reviewed journals
128 involving research supported by grants-in-aid awarded under the
129 program.

130 6. The total amount of biomedical research funding
131 currently flowing into the state.

132 7. New grants for biomedical research that were funded
133 based on research supported by grants-in-aid awarded under the
134 program.

135 8. All other materials the advisory council deems
136 advisable to include.

137 (d) Advisory council members shall disclose any conflict
138 of interest or potential conflict of interest to the Secretary
139 of Health.

140 (e) The Department of Health shall provide administrative

141 staff to assist the advisory council in developing the
 142 application for the grants-in-aid, reviewing the applications,
 143 preparing the written consent form described in paragraph
 144 (6) (b), and performing other administrative functions as the
 145 advisory council requires.

146 (4) BIOMEDICAL ETHICS ADVISORY COUNCIL.--There is created
 147 within the Department of Health the Biomedical Ethics Advisory
 148 Council.

149 (a)1. The advisory council shall consist of the Secretary
 150 of Health or his or her designee, who shall act as chair, and
 151 six additional members, who shall be appointed as follows:

152 a. Two persons appointed by the Governor.

153 b. One person appointed by the President of the Senate.

154 c. One person appointed by the Speaker of the House of
 155 Representatives.

156 d. One person appointed by the Minority Leader of the
 157 Senate.

158 e. One person appointed by the Minority Leader of the
 159 House of Representatives.

160 2. All members must demonstrate knowledge and
 161 understanding of the ethical, medical, and scientific
 162 implications of stem cell research and should also demonstrate
 163 knowledge of related fields, including, but not limited to,
 164 genetics, cellular biology, and embryology. Each member shall
 165 serve a term of 4 years commencing on October 1, 2007; however,
 166 for the purpose of providing staggered terms, of the initial
 167 appointments, three members shall be appointed to a 2-year term
 168 and three members shall be appointed to a 4-year term. No member

169 shall serve for more than two consecutive terms. Any vacancy on
170 the advisory council shall be filled in the same manner as the
171 original appointment. All initial appointments shall be made by
172 October 1, 2007. The first meeting shall take place no later
173 than November 1, 2007. All meetings are subject to the call of
174 the chair. Members shall meet at least twice a year or as often
175 as necessary to discharge their duties but shall have no more
176 than one meeting per month during any 12-month period. Members
177 shall serve without compensation but may be reimbursed for per
178 diem and travel expenses in accordance with s. 112.061.

179 (b) The advisory council shall review all stem cell
180 research that is funded or supported in any manner through the
181 Biomedical Research Trust Fund to ensure the adherence to
182 ethical and safety guidelines and procedures as set forth by
183 federal ethical standards established by the United States
184 Department of Health and Human Services.

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

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

189 (b) The Department of Health shall require any applicant
190 for a grant-in-aid under this section, for the purpose of
191 conducting stem cell research, to submit a complete description
192 of the applicant's organization, the applicant's plans for stem
193 cell research, the applicant's proposed funding for such
194 research from sources other than the state, and the applicant's
195 proposed arrangements concerning financial benefits to the state
196 as a result of any patent, royalty payment, or similar right

197 resulting from any stem cell research made possible by the
 198 awarding of the grant-in-aid. The Stem Cell Research Advisory
 199 Council shall provide recommendations to the Secretary of Health
 200 with respect to awarding such grants-in-aid after considering
 201 the recommendations of the Biomedical Ethics Advisory Council.

202 (c) Beginning with the 2007-2008 fiscal year, and for 10
 203 consecutive years thereafter, not less than \$20 million shall be
 204 made available annually from the Biomedical Research Trust Fund
 205 within the Department of Health for grants-in-aid to eligible
 206 institutions for the purpose of conducting adult stem cell
 207 research pursuant to this section. Up to 15 percent of the funds
 208 may be used for administrative costs. Any unexpended funds not
 209 used for grants-in-aid during the current fiscal year shall be
 210 carried forward for the following fiscal year to fund the
 211 grants-in-aid.

212 (6) USE OF FUNDS; REQUIREMENTS AND RESTRICTIONS.--

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

215 1. Human adult stem cells, including, but not limited to,
 216 adult stem cells derived from umbilical cord blood and bone
 217 marrow. Funding for research may be given for human adult stem
 218 cells derived from postmortem tissues, other than from medically
 219 induced abortions. Funds may be used for studies of human adult
 220 stem cells obtained from either normal or transformed tissues.

221 2. Amniotic stem cells extracted from human amniotic fluid
 222 or placentas that are otherwise discarded after birth.

223 (b) Amniotic and adult stem cell material may only be
 224 donated for research purposes with the informed consent of the

225 donor.

226 (c) No funds shall be used for research with human
 227 embryonic stem cells that are derived by a process entailing the
 228 donor embryo's death or destruction.

229 (7) HUMAN CLONING; PROHIBITION; PENALTIES.--

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

231 1. Perform or attempt to perform human cloning;

232 2. Participate or assist in an attempt to perform human
 233 cloning; or

234 3. Ship or receive for any purpose an embryo produced by
 235 human reproductive cloning or any product derived from such
 236 embryo.

237 (b) A person who violates paragraph (a) commits a felony
 238 of the second degree, punishable as provided in s. 775.082, s.
 239 775.083, or s. 775.084.

240 (8) CONTINUING APPROPRIATION.--Beginning in fiscal year
 241 2007-2008, the sum of \$20 million is appropriated annually from
 242 recurring funds in the General Revenue Fund to the Biomedical
 243 Research Trust Fund within the Department of Health for the
 244 purpose of carrying out the provisions of this section. The
 245 amount of funds appropriated shall not exceed \$200 million for
 246 the 10-year period beginning in fiscal year 2007-2008 and ending
 247 in fiscal year 2016-2017.

248 Section 2. Paragraph (h) of subsection (1) of section
 249 20.435, Florida Statutes, is amended to read:

250 20.435 Department of Health; trust funds.--

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

253 (h) Biomedical Research Trust Fund.

254 1. Funds to be credited to the trust fund shall consist of
255 funds deposited pursuant to ss. ~~s.~~ 215.5601, 288.955, and 381.99
256 and any other funds appropriated by the Legislature. Funds shall
257 be used for the purposes of the James and Esther King Biomedical
258 Research Program, and the William G. "Bill" Bankhead, Jr., and
259 David Coley Cancer Research Program, and the Florida Hope
260 Offered through Principled, Ethically Sound Stem Cell Research
261 Act as specified in ss. 215.5602, 288.955, and 381.922, and
262 381.99. The trust fund is exempt from the service charges
263 imposed by s. 215.20.

264 2. Notwithstanding the provisions of s. 216.301 and
265 pursuant to s. 216.351, any balance in the trust fund at the end
266 of any fiscal year shall remain in the trust fund at the end of
267 the year and shall be available for carrying out the purposes of
268 the trust fund. The department may invest these funds
269 independently through the Chief Financial Officer or may
270 negotiate a trust agreement with the State Board of
271 Administration for the investment management of any balance in
272 the trust fund.

273 3. Notwithstanding s. 216.301 and pursuant to s. 216.351,
274 any balance of any appropriation from the Biomedical Research
275 Trust Fund which is not disbursed but which is obligated
276 pursuant to contract or committed to be expended may be carried
277 forward for up to 3 years following the effective date of the
278 original appropriation.

279 4. The trust fund shall, unless terminated sooner, be
280 terminated on July 1, 2008.

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281 Section 3. Subsection (1) of section 381.86, Florida
282 Statutes, is amended to read:

283 381.86 Institutional Review Board.--

284 (1) The Institutional Review Board is created within the
285 Department of Health in order to satisfy federal requirements
286 under 45 C.F.R. part 46 and 21 C.F.R. parts 50 and 56 that an
287 institutional review board review all biomedical and behavioral
288 research on human subjects which is funded or supported in any
289 manner by the department, except that a separate Stem Cell
290 Research Advisory Council and Biomedical Ethics Advisory Council
291 shall be appointed under s. 381.99.

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