

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 Biomedical Research and  
8           Ethics Oversight Council; creating s. 381.99, F.S., the  
9           Florida Better Quality of Life and Biomedical Research  
10          Act; providing definitions; providing legislative  
11          findings; creating the Biomedical Research Advisory  
12          Council; providing for criteria, appointment, and terms of  
13          members; authorizing reimbursement for per diem and travel  
14          expenses; providing duties of the advisory council,  
15          including a report to the Governor, the President of the  
16          Senate, and the Speaker of the House of Representatives;  
17          requiring the Department of Health to provide  
18          administrative support; creating the Biomedical Research  
19          and Ethics Oversight Council to regulate research  
20          procedures and enforce ethical guidelines; providing for  
21          criteria, appointment, and terms of members; authorizing  
22          reimbursement for per diem and travel expenses; providing  
23          duties of the oversight council; providing for a grants-  
24          in-aid program for the purpose of conducting embryonic or  
25          human adult stem cell research; providing that grants-in-  
26          aid shall be provided through funds in the Biomedical  
27          Research Trust Fund; restricting the use of such funds for  
28          research on certain stem cells; providing requirements

29 with respect to the disposition of human embryos following  
 30 infertility treatment; requiring the Department of Health  
 31 to develop and maintain on its Internet website a consent  
 32 form for the donation of certain embryos; prohibiting  
 33 purchase or sale of embryonic fetal tissue for research  
 34 purposes; prohibiting certain acts relating to human  
 35 reproductive cloning; providing penalties; providing an  
 36 effective date.

37

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

39

40 Section 1. Paragraph (h) of subsection (1) of section  
 41 20.435, Florida Statutes, is amended to read:

42 20.435 Department of Health; trust funds.--

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

45 (h) Biomedical Research Trust Fund.

46 1. Funds to be credited to the trust fund shall consist of  
 47 funds deposited pursuant to ss. ~~s.~~ 215.5601, 288.955, and  
 48 381.99. Funds shall be used for the purposes of the James and  
 49 Esther King Biomedical Research Program as specified in ss.  
 50 215.5602 and 288.955 and the purposes of the Florida Better  
 51 Quality of Life and Biomedical Research Act as specified in s.  
 52 381.99. The trust fund is exempt from the service charges  
 53 imposed by s. 215.20.

54 2. Notwithstanding the provisions of s. 216.301 and  
 55 pursuant to s. 216.351, any balance in the trust fund at the end  
 56 of any fiscal year shall remain in the trust fund at the end of

57 | the year and shall be available for carrying out the purposes of  
 58 | the trust fund. The department may invest these funds  
 59 | independently through the Chief Financial Officer or may  
 60 | negotiate a trust agreement with the State Board of  
 61 | Administration for the investment management of any balance in  
 62 | the trust fund.

63 |         3. Notwithstanding s. 216.301 and pursuant to s. 216.351,  
 64 | any balance of any appropriation from the Biomedical Research  
 65 | Trust Fund which is not disbursed but which is obligated  
 66 | pursuant to contract or committed to be expended may be  
 67 | certified by the Governor for up to 3 years following the  
 68 | effective date of the original appropriation.

69 |         4. The trust fund shall, unless terminated sooner, be  
 70 | terminated on July 1, 2008.

71 |         Section 2. Subsection (1) of section 381.86, Florida  
 72 | Statutes, is amended to read:

73 |             381.86 Institutional Review Board.--

74 |             (1) The Institutional Review Board is created within the  
 75 | Department of Health in order to satisfy federal requirements  
 76 | under 45 C.F.R. part 46 and 21 C.F.R. parts 50 and 56 that an  
 77 | institutional review board review ~~all~~ biomedical and behavioral  
 78 | research on human subjects which is funded or supported in any  
 79 | manner by the department except for research within the  
 80 | jurisdiction of the Biomedical Research and Ethics Oversight  
 81 | Council, which shall be reviewed pursuant to the provisions of  
 82 | s. 381.99.

83 |         Section 3. Section 381.99, Florida Statutes, is created to  
 84 | read:

85           381.99 Florida Better Quality of Life and Biomedical  
 86 Research Act.--

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

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

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

94           (b) "Asexual reproduction" means reproduction not  
 95 initiated by the union of oocyte and sperm.

96           (c) "Embryonic stem cells" means cells obtained from the  
 97 undifferentiated inner mass of an early stage embryo.

98           (d) "Human reproductive cloning" means the practice of  
 99 creating or attempting to create a human being by transferring  
 100 the nucleus from a human cell into an egg cell from which the  
 101 nucleus has been removed for the purpose of implanting the  
 102 resulting product in a uterus or substitute for a uterus to  
 103 initiate a pregnancy.

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

108           (f) "Oocyte" means an immature egg cell of the human  
 109 ovary.

110           (g) "Stem cells" means undifferentiated cells which retain  
 111 the potential to differentiate into some or all other cell  
 112 types.

113 (3) LEGISLATIVE FINDINGS.--The Legislature finds that:

114 (a) An estimated 130 million Americans suffer from acute,  
115 chronic, and degenerative diseases and that there is enormous  
116 potential for lifesaving treatment and therapy as a result of  
117 recent advances in biomedical research.

118 (b) Florida is unique among all states for its large  
119 projected net population increase within the next 20 years. This  
120 increase, in turn, raises significant health care concerns as a  
121 new, larger generation of retirees moves to Florida, resulting  
122 in a corresponding rise in the number of persons suffering from  
123 illnesses such as cancer, heart disease, Alzheimer's Disease,  
124 Parkinson's Disease, cerebral palsy, juvenile diabetes,  
125 atherosclerosis, amyotrophic lateral sclerosis, AIDS, spinal  
126 cord injuries, severe burns, osteoporosis, osteoarthritis,  
127 cystic fibrosis, muscular dystrophy, multiple sclerosis, macular  
128 degeneration, diabetic retinopathy, retinitis pigmentosa,  
129 cirrhosis of the liver, motor neuron disease, brain trauma,  
130 stroke, sickle cell anemia, and intestinal diseases.

131 (c) In order to maintain a high quality of life for all  
132 Floridians, research into stem cell regenerative therapies and  
133 treatment should be supported to give hope and relief to the  
134 millions of citizens who suffer in silence from degenerative and  
135 crippling diseases.

136 (d) To reduce the burden on the health care  
137 infrastructure, the state must shift its health care objectives  
138 from costly long-term maintenance toward prevention and cures.

139 (e) To bolster and advance Florida's burgeoning  
140 biotechnology industry, the state should provide funds and  
141 incentives for private research companies to work in the state.

142 (f) The state should advance the goal of scientific and  
143 academic discourse in our universities and help bring its public  
144 and private universities to the forefront in biomedical research  
145 and technology.

146 (g) It will benefit the economy of the state to create a  
147 wide array of new projects and high-paying jobs relating to  
148 biomedical research.

149 (h) It will benefit the state to foster cooperation  
150 between the state's universities and private sector research in  
151 terms of jobs, resources, and academic discourse relating to  
152 biomedical research.

153 (i) The public funds provided under this section are  
154 intended to spur innovation and development in Florida's  
155 biomedical technology sector, which will be used to treat  
156 debilitating chronic diseases.

157 (4) BIOMEDICAL RESEARCH ADVISORY COUNCIL.--There shall be  
158 established a Biomedical Research Advisory Council.

159 (a) The advisory council shall consist of the Secretary of  
160 Health, who shall act as chair, and six additional members, who  
161 shall be appointed as follows:

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

165 2. One person appointed by the President of the Senate,  
166 who shall have a background in private sector stem cell funding

167 and development and public sector biomedical research and  
168 funding.

169 3. One person appointed by the Speaker of the House of  
170 Representatives, who shall have a background in private sector  
171 stem cell funding and development and public sector biomedical  
172 research and funding.

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

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

179  
180 Members shall serve for terms of 2 years each commencing on  
181 October 1, 2006. No member shall serve for more than two  
182 consecutive 2-year terms. All initial appointments must be made  
183 by October 1, 2006. The first meeting shall take place no later  
184 than November 1, 2006. Members shall meet at least twice  
185 annually, but no more than four times annually. Members shall  
186 serve without compensation but shall be reimbursed for per diem  
187 and travel expenses in accordance with s. 112.061.

188 (b) The members of the advisory council shall work to  
189 provide an environment fostering the advancement of embryonic  
190 and human adult stem cell research. The advisory council shall:

191 1. Develop a donated funds program for recommendation to  
192 the Secretary of Health, to encourage the development of funds  
193 other than state appropriations for embryonic and human adult  
194 stem cell research in the state.

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

204           3. Develop a biomedical research grant program for  
 205 recommendation to the Secretary Health, which shall provide  
 206 grants-in-aid to eligible institutions for the advancement of  
 207 embryonic or human adult stem cell research.

208           4. Develop, no later than December 1, 2006, an application  
 209 for grants-in-aid under this section for recommendation to the  
 210 Secretary of Health for the purpose of conducting embryonic or  
 211 human adult stem cell research.

212           5. Receive applications from eligible institutions for  
 213 grants-in-aid on and after December 1, 2006, and provide to the  
 214 Secretary of Health recommended grant awards.

215           6. Monitor the stem cell research conducted by eligible  
 216 institutions that receive such grants-in-aid.

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



- 223       1. The amount of grants-in-aid awarded to eligible  
224 institutions from the Biomedical Research Trust Fund.
- 225       2. The recipients of such grants-in-aid.
- 226       3. The current status and progress of stem cell research  
227 in the state.
- 228       4. A list of research projects supported by grants-in-aid  
229 awarded under the program.
- 230       5. A list of publications in peer-reviewed journals  
231 involving research supported by grants-in-aid awarded under the  
232 program.
- 233       6. The total amount of biomedical research funding  
234 currently flowing into the state.
- 235       7. New grants for biomedical research that were funded  
236 based on research supported by grants-in-aid awarded under the  
237 program.
- 238       8. All other materials the council deems advisable to  
239 include.
- 240       (d) Advisory council members shall disclose any conflict  
241 of interest or potential conflict of interest to the Secretary  
242 of Health.
- 243       (e) The Department of Health shall provide administrative  
244 staff to assist the advisory council in developing the  
245 application for the grants-in-aid, reviewing such applications,  
246 making recommendations to the advisory council, preparing the  
247 written consent form described in paragraph (7)(b), and  
248 performing other administrative functions as the advisory  
249 council requires or as is deemed necessary.

250           (5) BIOMEDICAL RESEARCH AND ETHICS OVERSIGHT  
 251 COUNCIL.--There shall be established a Biomedical Research and  
 252 Ethics Oversight Council.

253           (a) The oversight council shall consist of seven members,  
 254 of which the Secretary of Health shall act as chair. The  
 255 additional members shall be appointed as follows:

- 256           1. Two persons appointed by the Governor.
- 257           2. One person appointed by the President of the Senate.
- 258           3. One person appointed by the Speaker of the House of  
 259 Representatives.
- 260           4. One person appointed by the Minority Leader of the  
 261 Senate.
- 262           5. One person appointed by the Minority Leader of the  
 263 House of Representatives.

264  
 265 All members must demonstrate knowledge and understanding of the  
 266 ethical, medical, and scientific implications of embryonic and  
 267 adult stem cell research and should also demonstrate knowledge  
 268 of related fields, including, but not limited to, genetics,  
 269 cellular biology, and embryology. At least three members shall  
 270 have practical research experience in stem cell research or  
 271 related fields. Members shall serve for terms of 4 years each  
 272 commencing on October 1, 2006. No member shall serve for more  
 273 than two consecutive 4-year terms. All initial appointments must  
 274 be made by October 1, 2006. The first meeting shall take place  
 275 no later than November 1, 2006. Members shall meet at least  
 276 twice annually, but no more than four times annually. Members

277 shall serve without compensation but shall be reimbursed for per  
 278 diem and travel expenses in accordance with s. 112.061.

279 (b) The oversight council shall review all embryonic or  
 280 human adult stem cell research which is funded or supported in  
 281 any manner through the Biomedical Research Trust Fund to ensure  
 282 the adherence to ethical and safety guidelines and procedures as  
 283 laid out by federal ethical standards established by the United  
 284 States Department of Health and Human Services.

285 (6) BIOMEDICAL RESEARCH TRUST FUND AND GRANTS-IN-AID.--

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

289 (b) The Department of Health shall require any applicant  
 290 for a grant-in-aid under this section, for the purpose of  
 291 conducting stem cell research, to submit a complete description  
 292 of the applicant's organization, the applicant's plans for stem  
 293 cell research, the applicant's proposed funding for such  
 294 research from sources other than the state, and the applicant's  
 295 proposed arrangements concerning financial benefits to the state  
 296 as a result of any patent, royalty payment, or similar rights  
 297 resulting from any stem cell research made possible by the  
 298 awarding of such grant-in-aid. The Biomedical Research Advisory  
 299 Council shall provide recommendations to the Secretary of Health  
 300 with respect to awarding such grants-in-aid after considering  
 301 recommendations from the Biomedical Research and Ethics  
 302 Oversight Council.

303 (c) Beginning with the 2006-2007 fiscal year, and for 10  
 304 consecutive years thereafter, not less than \$15 million shall be

305 made available annually from the Biomedical Research Trust Fund  
 306 for grants-in-aid to eligible institutions for the purpose of  
 307 conducting embryonic or human adult stem cell research as  
 308 directed by the Biomedical Research Advisory Council. Any  
 309 balance of such amount not used for such grants-in-aid during a  
 310 fiscal year shall be carried forward for the fiscal year next  
 311 succeeding for such grants-in-aid.

312 (7) FUNDING.--Funds provided under this section may only  
 313 be used for research involving:

314 (a) Human adult stem cells, including, but not limited to,  
 315 adult stem cells derived from umbilical cord blood and bone  
 316 marrow.

317 (b) Human embryonic stem cells taken from donated leftover  
 318 embryos from in vitro fertilization treatments that would  
 319 otherwise be thrown away or destroyed.

320 1. A physician or other health care provider who is  
 321 treating a patient for infertility shall provide the patient  
 322 with timely, relevant, and appropriate information sufficient to  
 323 allow the person to make an informed and voluntary choice  
 324 regarding the disposition of any human embryos that remain  
 325 following infertility treatment.

326 2. A person to whom information is provided pursuant to  
 327 subparagraph 1. shall be presented with the options of storing  
 328 any unused embryos, donating them to another person, donating  
 329 the remaining embryos for research purposes, or selecting other  
 330 means of disposition.

331 3. A person who elects to donate, for research purposes,  
 332 any embryos remaining after receiving infertility treatment

333 shall provide written consent for that donation in a consent  
 334 form provided by the Department of Health and made available to  
 335 the public on the department's Internet website.

336 4. A person may not knowingly, for material or financial  
 337 gain, purchase, sell, or otherwise transfer or obtain, or  
 338 promote the sale or transfer of, embryonic fetal tissue for  
 339 research purposes pursuant to this section. Embryonic and adult  
 340 stem cell material may only be donated for research purposes  
 341 with the informed consent of the donor. A person who violates  
 342 any provision of this subparagraph commits a felony of the  
 343 second degree, punishable as provided in s. 775.082, s. 775.083,  
 344 or s. 775.084.

345 (8) HUMAN REPRODUCTIVE CLONING; PROHIBITION; PENALTIES.--

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

347 1. Perform or attempt to perform human reproductive  
 348 cloning.

349 2. Participate or assist in an attempt to perform human  
 350 reproductive cloning.

351 3. Ship or receive for any purpose an embryo produced by  
 352 human reproductive cloning or any product derived from such  
 353 embryo.

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

357 Section 4. This act shall take effect July 1, 2006.