

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 and Ethics Advisory  
5           Council within the Department of Health; providing for  
6           membership and terms; providing duties and  
7           responsibilities; providing per diem and travel expenses,  
8           subject to a specific appropriation; requiring the  
9           Secretary of Health to make grants-in-aid from the  
10          Biomedical Research Trust Fund for stem cell research  
11          subject to a specific appropriation; providing  
12          requirements relating to applications for and awards of  
13          such grants-in-aid; providing specifications for moneys to  
14          be made available from the trust fund for stem cell  
15          research grants-in-aid; providing restrictions and  
16          requirements for uses of funds from such grants-in-aid;  
17          amending s. 20.435, F.S.; revising provisions relating to  
18          funding sources of and use of funds in the Biomedical  
19          Research Trust Fund; amending s. 381.86, F.S.; providing  
20          an exception to the Institutional Review Board's exclusive  
21          authority to review certain biomedical and behavioral  
22          research on human subjects to allow for the Stem Cell  
23          Research and Ethics Advisory Council's duties and  
24          responsibilities with respect to such research; requiring  
25          the Department of Health to prepare and distribute,  
26          subject to a specific appropriation, a publication  
27          regarding the process, options, medical uses, risks, and

28 |           benefits of umbilical cord blood collection; providing an  
 29 |           effective date.

31 | Be It Enacted by the Legislature of the State of Florida:

33 |           Section 1. Section 381.99, Florida Statutes, is created to  
 34 | read:

35 |           381.99 Florida Hope Offered through Principled, Ethically  
 36 | Sound Stem Cell Research Act.--

37 |           (1) SHORT TITLE.--This section may be cited as the  
 38 | "Florida Hope Offered through Principled, Ethically Sound Stem  
 39 | Cell Research Act."

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

41 |           (a) "Adult stem cell" means a cell found within  
 42 | differentiated tissue or an organ that can renew itself and give  
 43 | rise to the major cell types of the tissue or organ. This  
 44 | includes cells from the fetal to adult stages of development,  
 45 | including bone marrow.

46 |           (b) "Amniotic stem cell" means a stem cell extracted from  
 47 | human amniotic fluid.

48 |           (c) "Cord blood stem cell" means a stem cell extracted  
 49 | from a human umbilical cord.

50 |           (d) "Placental stem cell" means a stem cell extracted from  
 51 | a human placenta.

52 |           (e) "Embryonic stem cell" means a stem cell obtained from  
 53 | the undifferentiated inner mass of an early stage embryo.

54 |           (f) "Stem cell" means a cell that can renew itself and  
 55 | retains the potential to generate some or all other cell types.

56        (3) STEM CELL RESEARCH AND ETHICS ADVISORY COUNCIL.--There  
57 is created the Stem Cell Research and Ethics Advisory Council  
58 within the Department of Health.

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

62        a. Two persons appointed by the Governor, one of whom  
63 shall be an academic researcher in the field of stem cell  
64 research and one of whom shall have a background in bioethics.

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

69        c. One person appointed by the Speaker of the House of  
70 Representatives, who shall have a background in private-sector  
71 stem cell funding and development or public-sector biomedical  
72 research and funding.

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

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

79        2. Each member shall demonstrate knowledge and  
80 understanding of the ethical, medical, and scientific  
81 implications of stem cell research. Each member shall serve a  
82 term of 2 years commencing on July 15, 2007. No member shall  
83 serve for more than two consecutive 2-year terms; however, for

84 the purpose of providing staggered terms, of the initial  
85 appointments, three members shall be appointed to a 1-year term  
86 and three members shall be appointed to a 2-year term. Any  
87 vacancy on the advisory council shall be filled in the same  
88 manner as the original appointment. All initial appointments  
89 shall be made by July 15, 2007. The first meeting shall take  
90 place no later than August 15, 2007. All meetings are subject to  
91 the call of the chair. Members shall meet at least twice a year  
92 or as often as necessary to discharge their duties but shall  
93 have no more than four meetings during any 12-month period.  
94 Members shall serve without compensation but may be reimbursed  
95 for per diem and travel expenses in accordance with s. 112.061,  
96 subject to a specific appropriation in the General  
97 Appropriations Act.

98 (b) The advisory council shall:

99 1. Develop a donated funds program for recommendation to  
100 the Secretary of Health to encourage the development of funds  
101 other than state appropriations for human adult, amniotic, cord  
102 blood, and placental stem cell research in the state.

103 2. Examine and identify specific ways to improve and  
104 promote for-profit and not-for-profit human adult, amniotic,  
105 cord blood, and placental stem cell and related research in the  
106 state, including, but not limited to, identifying both public  
107 and private funding sources for such research, maintaining  
108 existing human adult, amniotic, cord blood, and placental stem  
109 cell-related businesses, recruiting new human adult, amniotic,  
110 cord blood, and placental stem cell-related businesses to the  
111 state, and recruiting scientists and researchers in such fields

112 to the state and state universities.

113 3. Develop a biomedical research grant program for  
114 recommendation to the Secretary of Health that shall provide  
115 grants-in-aid to eligible state institutions for the advancement  
116 of human adult, amniotic, cord blood, and placental stem cell  
117 research.

118 4. Develop, no later than September 15, 2007, an  
119 application for grants-in-aid under this section for  
120 recommendation to the Secretary of Health for the purpose of  
121 conducting human adult, amniotic, cord blood, and placental stem  
122 cell research.

123 5. Review applications from eligible institutions for  
124 grants-in-aid on and after September 15, 2007, and provide to  
125 the Secretary of Health recommendations for grant awards.

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

128 7. Review all stem cell research that is funded or  
129 supported in any manner through the Biomedical Research Trust  
130 Fund to ensure the adherence to ethical and safety guidelines  
131 and procedures as set forth by federal ethical standards  
132 established by the United States Department of Health and Human  
133 Services.

134 (c) The advisory council shall submit an annual progress  
135 report on the status of biomedical research in the state to the  
136 Florida Center for Universal Research to Eradicate Disease and  
137 to the Governor, the Secretary of Health, the President of the  
138 Senate, and the Speaker of the House of Representatives by June  
139 30. The report must include:

- 140        1. The amount of grants-in-aid awarded to eligible  
 141 institutions from the Biomedical Research Trust Fund.
- 142        2. The names of the recipients of such grants-in-aid.
- 143        3. The current status and progress of stem cell research  
 144 in the state.
- 145        4. A list of research projects supported by grants-in-aid  
 146 awarded under the program.
- 147        5. A list of publications in peer-reviewed journals  
 148 involving research supported by grants-in-aid awarded under the  
 149 program.
- 150        6. The total amount of biomedical research funding  
 151 currently flowing into the state.
- 152        7. New grants for biomedical research that were funded  
 153 based on research supported by grants-in-aid awarded under the  
 154 program.
- 155        8. All other materials the advisory council deems  
 156 advisable to include.
- 157        (d) Advisory council members shall disclose any conflict  
 158 of interest or potential conflict of interest to the Secretary  
 159 of Health.
- 160        (e) The Department of Health shall provide administrative  
 161 staff to assist the advisory council in developing the  
 162 application for the grants-in-aid, reviewing the applications,  
 163 preparing the written consent form described in paragraph  
 164 (5) (b), and performing other administrative functions as the  
 165 advisory council requires.
- 166        (4) BIOMEDICAL RESEARCH TRUST FUND AND GRANTS-IN-AID.--
- 167        (a) The Secretary of Health shall make grants-in-aid from

168 the Biomedical Research Trust Fund in accordance with the  
 169 provisions of this section, subject to a specific appropriation  
 170 in the General Appropriations Act.

171 (b) The Department of Health shall require any applicant  
 172 for a grant-in-aid under this section, for the purpose of  
 173 conducting stem cell research, to submit a complete description  
 174 of the applicant's organization, the applicant's plans for stem  
 175 cell research, the applicant's proposed funding for such  
 176 research from sources other than the state, and the applicant's  
 177 proposed arrangements concerning financial benefits to the state  
 178 as a result of any patent, royalty payment, or similar right  
 179 resulting from any stem cell research made possible by the  
 180 awarding of the grant-in-aid. The advisory council shall provide  
 181 recommendation to the Secretary of Health with respect to  
 182 awarding such grants-in-aid.

183 (5) USE OF FUNDS; REQUIREMENTS AND RESTRICTIONS.--

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

186 1. Human adult stem cells. Funding for research may be  
 187 given for human adult stem cells derived from postmortem  
 188 tissues, other than from medically induced abortions. Funds may  
 189 be used for studies of human adult stem cells obtained from  
 190 either normal or transformed tissues.

191 2. Amniotic stem cells extracted from human amniotic fluid  
 192 that are otherwise discarded after birth.

193 3. Cord blood stem cells extracted from a human umbilical  
 194 cord that are otherwise discarded after birth.

195 4. Placental stem cells extracted from a human placenta

196 that are otherwise discarded after birth.

197 (b) Adult, amniotic, cord blood, and placental stem cell  
 198 material may only be donated for research purposes with the  
 199 informed consent of the donor.

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

203 (d) Funds provided under this section may only be used for  
 204 research that is conducted in facilities located in this state.

205 Section 2. Paragraph (h) of subsection (1) of section  
 206 20.435, Florida Statutes, is amended to read:

207 20.435 Department of Health; trust funds.--

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

210 (h) Biomedical Research Trust Fund.

211 1. Funds to be credited to the trust fund shall consist of  
 212 funds deposited pursuant to ss. ~~215.5601~~, 288.955, and 381.99  
 213 and any other funds appropriated by the Legislature. Funds shall  
 214 be used for the purposes of the James and Esther King Biomedical  
 215 Research Program, and the William G. "Bill" Bankhead, Jr., and  
 216 David Coley Cancer Research Program, and the Florida Hope  
 217 Offered through Principled, Ethically Sound Stem Cell Research  
 218 Act as specified in ss. 215.5602, 288.955, ~~and 381.922~~, and  
 219 381.99. The trust fund is exempt from the service charges  
 220 imposed by s. 215.20.

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



224 the year and shall be available for carrying out the purposes of  
 225 the trust fund. The department may invest these funds  
 226 independently through the Chief Financial Officer or may  
 227 negotiate a trust agreement with the State Board of  
 228 Administration for the investment management of any balance in  
 229 the trust fund.

230 3. Notwithstanding s. 216.301 and pursuant to s. 216.351,  
 231 any balance of any appropriation from the Biomedical Research  
 232 Trust Fund which is not disbursed but which is obligated  
 233 pursuant to contract or committed to be expended may be carried  
 234 forward for up to 3 years following the effective date of the  
 235 original appropriation.

236 4. The trust fund shall, unless terminated sooner, be  
 237 terminated on July 1, 2008.

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

240 381.86 Institutional Review Board.--

241 (1) The Institutional Review Board is created within the  
 242 Department of Health in order to satisfy federal requirements  
 243 under 45 C.F.R. part 46 and 21 C.F.R. parts 50 and 56 that an  
 244 institutional review board review all biomedical and behavioral  
 245 research on human subjects which is funded or supported in any  
 246 manner by the department, except that a separate Stem Cell  
 247 Research and Ethics Advisory Council shall be appointed under s.  
 248 381.99.

249 Section 4. (1) The Department of Health shall prepare an  
 250 educational publication, subject to a specific appropriation in  
 251 the General Appropriations Act, that includes objective

252 information regarding:

253 (a) The medical processes involved in the collection of  
 254 umbilical cord blood;

255 (b) The medical risks to the mother and her newborn child  
 256 of umbilical cord blood collection;

257 (c) The options available to a mother relating to stem  
 258 cells that are contained in the umbilical cord blood after the  
 259 delivery of her newborn, including:

260 1. Discarding the stem cells;

261 2. Donating the stem cells to a public umbilical cord  
 262 blood bank;

263 3. Storing the stem cells in a family or private umbilical  
 264 cord blood bank for use by family members; or

265 4. Storing the stem cells for family use through a family  
 266 or sibling donor banking program that provides free collection,  
 267 processing, and storage where there is a medical need;

268 (d) The current and potential future medical uses, risks,  
 269 and benefits of umbilical cord blood collection to a mother, her  
 270 newborn child, and her biological family;

271 (e) The current and potential future medical uses, risks,  
 272 and benefits of umbilical cord blood collection to persons who  
 273 are not biologically related to a mother or her newborn child;

274 (f) Any costs that may be incurred by a pregnant woman who  
 275 chooses to make an umbilical cord blood donation;

276 (g) Options for ownership and future use of the donated  
 277 umbilical cord blood; and

278 (h) The average cost of public and private umbilical cord  
 279 blood banking.

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280           (2) The department shall update the publication as  
281 necessary.

282           (3) The department shall distribute the publication free  
283 of charge to physicians and health care institutions on request  
284 and shall make the publication available on its website in a  
285 printable format.

286           (4) The department shall encourage health and maternal  
287 care professionals providing health care services to a pregnant  
288 woman, when those health care services are directly related to  
289 her pregnancy, to provide the pregnant woman with the  
290 publication by the end of her second trimester.

291           Section 5. This act shall take effect July 1, 2007.