



1 grants-in-aid shall be provided through funds  
2 in the Biomedical Research Trust Fund;  
3 restricting the use of such funds for research  
4 on certain stem cells; providing requirements  
5 with respect to the disposition of human  
6 embryos following infertility treatment;  
7 requiring the Department of Health to develop  
8 and maintain on its Internet website a consent  
9 form for the donation of certain embryos;  
10 prohibiting the purchase or sale of embryonic  
11 fetal tissue for research purposes; prohibiting  
12 certain acts relating to human reproductive  
13 cloning; providing penalties; providing an  
14 effective date.

15  
16 Be It Enacted by the Legislature of the State of Florida:

17  
18 Section 1. Paragraph (h) of subsection (1) of section  
19 20.435, Florida Statutes, is amended to read:

20 20.435 Department of Health; trust funds.--

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

23 (h) Biomedical Research Trust Fund.

24 1. Funds to be credited to the trust fund shall  
25 consist of funds deposited pursuant to ss. ~~s.~~ 215.5601,  
26 288.955, and 381.99. Funds shall be used for the purposes of  
27 the James and Esther King Biomedical Research Program as  
28 specified in ss. 215.5602 and 288.955 and the purposes of the  
29 Florida Better Quality of Life and Biomedical Research Act as  
30 specified in s. 381.99. The trust fund is exempt from the  
31 service charges imposed by s. 215.20.

1           2. Notwithstanding the provisions of s. 216.301 and  
2 pursuant to s. 216.351, any balance in the trust fund at the  
3 end of any fiscal year shall remain in the trust fund at the  
4 end of the year and shall be available for carrying out the  
5 purposes of the trust fund. The department may invest these  
6 funds independently through the Chief Financial Officer or may  
7 negotiate a trust agreement with the State Board of  
8 Administration for the investment management of any balance in  
9 the trust fund.

10           3. Notwithstanding s. 216.301 and pursuant to s.  
11 216.351, any balance of any appropriation from the Biomedical  
12 Research Trust Fund which is not disbursed but which is  
13 obligated pursuant to contract or committed to be expended may  
14 be certified by the Governor for up to 3 years following the  
15 effective date of the original appropriation.

16           4. The trust fund shall, unless terminated sooner, be  
17 terminated on July 1, 2008.

18           Section 2. Subsection (1) of section 381.86, Florida  
19 Statutes, is amended to read:

20           381.86 Institutional Review Board.--

21           (1) The Institutional Review Board is created within  
22 the Department of Health in order to satisfy federal  
23 requirements under 45 C.F.R. part 46 and 21 C.F.R. parts 50  
24 and 56 that an institutional review board review ~~all~~  
25 biomedical and behavioral research on human subjects which is  
26 funded or supported in any manner by the department except for  
27 research within the jurisdiction of the Biomedical Research  
28 and Ethics Oversight Council, which shall be reviewed pursuant  
29 to the provisions of s. 381.99.

30           Section 3. Section 381.99, Florida Statutes, is  
31 created to read:

1           381.99 Florida Better Quality of Life and Biomedical  
2 Research Act.--

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

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

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

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

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

14          (d) "Human reproductive cloning" means the practice of  
15 creating or attempting to create a human being by transferring  
16 the nucleus from a human cell into an egg cell from which the  
17 nucleus has been removed for the purpose of implanting the  
18 resulting product in a uterus or substitute for a uterus to  
19 initiate a pregnancy.

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

24          (f) "Oocyte" means an immature egg cell of the human  
25 ovary.

26          (g) "Stem cells" means undifferentiated cells which  
27 retain the potential to differentiate into some or all other  
28 cell types.

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

30          (a) An estimated 130 million Americans suffer from  
31 acute, chronic, and degenerative diseases and that there is

1 enormous potential for lifesaving treatment and therapy as a  
2 result of recent advances in biomedical research.

3 (b) Florida is unique among all states for its large  
4 projected net population increase within the next 20 years.  
5 This increase, in turn, raises significant health care  
6 concerns as a new, larger generation of retirees moves to this  
7 state, resulting in a corresponding rise in the number of  
8 persons suffering from illnesses such as cancer, heart  
9 disease, Alzheimer's Disease, Parkinson's Disease, cerebral  
10 palsy, atherosclerosis, amyotrophic lateral sclerosis, AIDS,  
11 spinal cord injuries, severe burns, osteoporosis,  
12 osteoarthritis, cystic fibrosis, muscular dystrophy, multiple  
13 sclerosis, macular degeneration, diabetic retinopathy,  
14 retinitis pigmentosa, cirrhosis of the liver, motor neuron  
15 disease, brain trauma, stroke, sickle cell anemia, and  
16 intestinal diseases. Juvenile diabetes is becoming more  
17 prevalent in children in this state.

18 (c) In order to maintain a high quality of life for  
19 all Floridians, research into stem cell regenerative therapies  
20 and treatment, among other therapies and treatments, should be  
21 supported to give hope and relief to the millions of residents  
22 who suffer in silence from degenerative and crippling  
23 diseases.

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

28 (e) To bolster and advance Florida's burgeoning  
29 biotechnology industry, the state should continue to provide  
30 funds and incentives for private research companies to work in  
31 the state.

1       (f) The state should advance the goal of scientific  
2 and academic discourse in our colleges, universities, and  
3 private research institutions and should continue to help  
4 bring these institutions to the forefront in biomedical  
5 research and technology.

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

9       (h) It will benefit the state to foster cooperation  
10 between the state's colleges, universities, and private-sector  
11 research in terms of jobs, resources, and academic discourse  
12 relating to biomedical research.

13       (i) The public funds provided under this section are  
14 intended to spur innovation and development in the state's  
15 biomedical technology sector, which will be used to treat  
16 debilitating chronic diseases.

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

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

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

25       2. One person appointed by the President of the  
26 Senate, who shall have a background in private sector stem  
27 cell funding and development and public sector biomedical  
28 research and funding.

29       3. One person appointed by the Speaker of the House of  
30 Representatives, who shall have a background in private-sector  
31

1 stem cell funding and development and public-sector biomedical  
2 research and funding.

3 4. One person appointed by the Minority Leader of the  
4 Senate, who shall have a background and experience in  
5 public-sector or private-sector stem cell research and  
6 development.

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

10  
11 Members shall be appointed to terms of 2 years each commencing  
12 on October 1, 2006. A member may not serve for more than two  
13 consecutive 2-year terms. All initial appointments must be  
14 made by October 1, 2006. The first meeting shall take place no  
15 later than November 1, 2006. Members shall meet at least twice  
16 annually, but no more than four times annually. Members shall  
17 serve without compensation but are entitled to reimbursement  
18 for per diem and travel expenses in accordance with s.  
19 112.061.

20 (b) The members of the advisory council shall work to  
21 provide an environment fostering the advancement of embryonic  
22 and human adult stem cell research. The advisory council  
23 shall:

24 1. Develop a donated-funds program for recommendation  
25 to the Secretary of Health, to encourage the development of  
26 funds other than state appropriations for embryonic and human  
27 adult stem cell research in the state.

28 2. Examine and identify specific ways to improve and  
29 promote for-profit and not-for-profit embryonic and human  
30 adult stem cell and related research in the state, including,  
31 but not limited to, identifying both public and private

1 funding sources for such research, maintaining existing  
2 activities related to embryonic and human adult stem cell  
3 research, recruiting new activities to the state related to  
4 embryonic and human adult stem cell research, and recruiting  
5 scientists and researchers in such fields to the state and  
6 state universities.

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

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

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

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

20 (c) The advisory council shall submit an annual  
21 progress report on the state of biomedical research in the  
22 state to the Florida Center for Universal Research to  
23 Eradicate Disease and to the Governor, the Secretary of  
24 Health, the President of the Senate, and the Speaker of the  
25 House of Representatives by June 30. The report must include:

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

28 2. The recipients of such grants-in-aid.

29 3. The current status and progress of stem cell  
30 research in the state.

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

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

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

8           7. New grants for biomedical research that were funded  
9 based on research supported by grants-in-aid awarded under the  
10 program.

11           8. All other materials the council deems advisable to  
12 include.

13           (d) Advisory council members shall disclose any  
14 conflict of interest or potential conflict of interest to the  
15 Secretary of Health.

16           (e) The Department of Health shall provide  
17 administrative staff to assist the advisory council in  
18 developing the application for the grants-in-aid, reviewing  
19 such applications, making recommendations to the advisory  
20 council, preparing the written consent form described in  
21 paragraph (7)(b), and performing other administrative  
22 functions as the advisory council requires or as is deemed  
23 necessary.

24           (5) BIOMEDICAL RESEARCH AND ETHICS OVERSIGHT  
25 COUNCIL.--There shall be established a Biomedical Research and  
26 Ethics Oversight Council.

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

30           1. Two persons appointed by the Governor.  
31

1           2. One person appointed by the President of the  
2 Senate.

3           3. One person appointed by the Speaker of the House of  
4 Representatives.

5           4. One person appointed by the Minority Leader of the  
6 Senate.

7           5. One person appointed by the Minority Leader of the  
8 House of Representatives.

9  
10 All members must demonstrate knowledge and understanding of  
11 the ethical, medical, and scientific implications of embryonic  
12 and adult stem cell research and should also demonstrate  
13 knowledge of related fields, including, but not limited to,  
14 genetics, cellular biology, and embryology. At least three  
15 members shall have practical research experience in stem cell  
16 research or related fields. Members shall be appointed to  
17 terms of 4 years each commencing on October 1, 2006. A member  
18 may not serve for more than two consecutive 4-year terms. All  
19 initial appointments must be made by October 1, 2006. The  
20 first meeting shall take place no later than November 1, 2006.  
21 Members shall meet at least twice annually, but no more than  
22 four times annually. Members shall serve without compensation  
23 but are entitled to reimbursement for per diem and travel  
24 expenses in accordance with s. 112.061.

25           (b) The oversight council shall review all embryonic  
26 or human adult stem cell research that is funded or supported  
27 in any manner through the Biomedical Research Trust Fund to  
28 ensure the adherence to ethical and safety guidelines and  
29 procedures as laid out by federal ethical standards  
30 established by the United States Department of Health and  
31 Human Services.

1           (6) BIOMEDICAL RESEARCH TRUST FUND AND

2 GRANTS-IN-AID.--

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

6           (b) The Department of Health shall require any  
7 applicant for a grant-in-aid under this section, for the  
8 purpose of conducting stem cell research, to submit a complete  
9 description of the applicant's organization, the applicant's  
10 plans for stem cell research, the applicant's proposed funding  
11 for such research from sources other than the state, and the  
12 applicant's proposed arrangements concerning financial  
13 benefits to the state as a result of any patent, royalty  
14 payment, or similar rights resulting from any stem cell  
15 research made possible by the awarding of such grant-in-aid.  
16 The Biomedical Research Advisory Council shall provide  
17 recommendations to the Secretary of Health with respect to  
18 awarding such grants-in-aid after considering recommendations  
19 from the Biomedical Research and Ethics Oversight Council.

20           (c) Beginning with the 2006-2007 fiscal year, and for  
21 10 consecutive years thereafter, not less than \$15 million  
22 shall be made available annually from the Biomedical Research  
23 Trust Fund for grants-in-aid to eligible institutions for the  
24 purpose of conducting embryonic or human adult stem cell  
25 research as directed by the Biomedical Research Advisory  
26 Council. Any balance of such amount not used for such  
27 grants-in-aid during a fiscal year shall be carried forward  
28 for the fiscal year next succeeding for such grants-in-aid.

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

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1       (a) Human adult stem cells, including, but not limited  
2 to, adult stem cells derived from umbilical cord blood and  
3 bone marrow.

4       (b) Human embryonic stem cells taken from donated  
5 leftover embryos from in vitro fertilization treatments which  
6 would otherwise be thrown away or destroyed.

7           1. A physician or other health care provider who is  
8 treating a patient for infertility shall provide the patient  
9 with timely, relevant, and appropriate information sufficient  
10 to allow the person to make an informed and voluntary choice  
11 regarding the disposition of any human embryos that remain  
12 following infertility treatment.

13           2. A person to whom information is provided pursuant  
14 to subparagraph 1. shall be presented with the options of  
15 storing any unused embryos, donating them to another person,  
16 donating the remaining embryos for research purposes, or  
17 selecting other means of disposition.

18           3. A person who elects to donate, for research  
19 purposes, any embryos remaining after receiving infertility  
20 treatment shall provide written consent for that donation in a  
21 consent form provided by the Department of Health and made  
22 available to the public on the department's Internet website.

23           4. A person may not knowingly, for material or  
24 financial gain, purchase, sell, or otherwise transfer or  
25 obtain, or promote the sale or transfer of, embryonic fetal  
26 tissue for research purposes pursuant to this section.  
27 Embryonic and adult stem cell material may be donated only for  
28 research purposes with the informed consent of the donor. A  
29 person who violates this subparagraph commits a felony of the  
30 second degree, punishable as provided in s. 775.082, s.  
31 775.083, or s. 775.084.

- 1           (8) HUMAN REPRODUCTIVE CLONING; PROHIBITION;  
2 PENALTIES.--  
3           (a) A person may not knowingly:  
4           1. Perform or attempt to perform human reproductive  
5 cloning.  
6           2. Participate or assist in an attempt to perform  
7 human reproductive cloning.  
8           3. Ship or receive for any purpose an embryo produced  
9 by human reproductive cloning or any product derived from such  
10 embryo.  
11           (b) A person who violates paragraph (a) commits a  
12 felony of the second degree, punishable as provided in s.  
13 775.082, s. 775.083, or s. 775.084.

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

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17           SENATE SUMMARY

18           Revises uses for funds credited to the Biomedical  
19           Research Trust Fund. Provides that the Institutional  
20           Review Board within the Department of Health may not  
21           review certain research within the jurisdiction of the  
22           Biomedical Research and Ethics Oversight Council. Creates  
23           the Florida Better Quality of Life and Biomedical  
24           Research Act. Creates the Biomedical Research Advisory  
25           Council. Provides duties of the advisory council,  
26           including a report to the Governor, the President of the  
27           Senate, and the Speaker of the House of Representatives.  
28           Requires the Department of Health to provide  
29           administrative support. Creates the Biomedical Research  
30           and Ethics Oversight Council. Provides duties of the  
31           oversight council. Provides for a grants-in-aid program  
          for the purpose of conducting embryonic or human adult  
          stem cell research. Provides that grants-in-aid shall be  
          provided through funds in the Biomedical Research Trust  
          Fund. Restricts the use of such funds for research on  
          certain stem cells. Provides requirements with respect to  
          the disposition of human embryos following infertility  
          treatment. Requires the Department of Health to develop  
          and maintain on its Internet website a consent form for  
          the donation of certain embryos. Prohibits purchase or  
          sale of embryonic fetal tissue for research purposes.  
          Prohibits certain acts relating to human reproductive  
          cloning. Provides penalties.