

By the Committees on Commerce; Health Policy; and Senator
Haridopolos

577-2475-07

1 A bill to be entitled
2 An act relating to stem cell research; creating
3 s. 381.99, F.S.; providing a short title;
4 providing definitions; creating the Stem Cell
5 Research and Ethics Advisory Council within the
6 Department of Health; providing for membership
7 and terms; providing duties and
8 responsibilities; providing per diem and travel
9 expenses, subject to a specific appropriation;
10 requiring the Secretary of Health to make
11 grants-in-aid from the Biomedical Research
12 Trust Fund for stem cell research subject to a
13 specific appropriation; providing requirements
14 relating to applications for and awards of such
15 grants-in-aid; providing specifications for
16 moneys to be made available from the trust fund
17 for stem cell research grants-in-aid; providing
18 restrictions and requirements for uses of funds
19 from such grants-in-aid; amending s. 20.435,
20 F.S.; revising provisions relating to funding
21 sources of and use of funds in the Biomedical
22 Research Trust Fund; amending s. 381.86, F.S.;
23 providing an exception to the Institutional
24 Review Board's exclusive authority to review
25 certain biomedical and behavioral research on
26 human subjects to allow for the Stem Cell
27 Research and Ethics Advisory Council's duties
28 and responsibilities with respect to such
29 research; requiring the Department of Health to
30 prepare and distribute, subject to a specific
31 appropriation, a publication regarding the

1 process, options, medical uses, risks, and
2 benefits of umbilical cord blood collection;
3 providing an effective date.
4

5 Be It Enacted by the Legislature of the State of Florida:
6

7 Section 1. Section 381.99, Florida Statutes, is
8 created to read:

9 381.99 Florida Hope Offered through Principled,
10 Ethically Sound Stem Cell Research Act.--

11 (1) SHORT TITLE.--This section may be cited as the
12 "Florida Hope Offered through Principled, Ethically Sound Stem
13 Cell Research Act."

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

15 (a) "Adult stem cell" means a cell found within
16 differentiated tissue or an organ that can renew itself and
17 give rise to the major cell types of the tissue or organ. This
18 includes cells from the fetal to adult stages of development,
19 including bone marrow.

20 (b) "Amniotic stem cell" means a stem cell extracted
21 from human amniotic fluid.

22 (c) "Cord blood stem cell" means a stem cell extracted
23 from a human umbilical cord.

24 (d) "Placental stem cell" means a stem cell extracted
25 from a human placenta.

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

28 (f) "Stem cell" means a cell that can renew itself and
29 retains the potential to generate some or all other cell
30 types.
31

1 (3) STEM CELL RESEARCH AND ETHICS ADVISORY
2 COUNCIL.--There is created the Stem Cell Research and Ethics
3 Advisory Council within the Department of Health.
4 (a)1. The advisory council shall consist of the
5 Secretary of Health or his or her designee, who shall act as
6 chair, and six additional members, who shall be appointed as
7 follows:
8 a. Two persons appointed by the Governor, one of whom
9 shall be an academic researcher in the field of stem cell
10 research and one of whom shall have a background in bioethics.
11 b. One person appointed by the President of the
12 Senate, who shall have a background in private-sector stem
13 cell funding and development or public-sector biomedical
14 research and funding.
15 c. One person appointed by the Speaker of the House of
16 Representatives, who shall have a background in private-sector
17 stem cell funding and development or public-sector biomedical
18 research and funding.
19 d. One person appointed by the President of the
20 Senate, who shall have a background and experience in either
21 public-sector or private-sector stem cell research and
22 development.
23 e. One person appointed by the Speaker of the House of
24 Representatives, who shall be an executive of a biotech
25 company, or his or her designee.
26 2. Each member shall demonstrate knowledge and
27 understanding of the ethical, medical, and scientific
28 implications of stem cell research. Each member shall serve a
29 term of 2 years commencing on July 15, 2007. No member shall
30 serve for more than two consecutive 2-year terms; however, for
31 the purpose of providing staggered terms, of the initial

1 appointments, three members shall be appointed to a 1-year
2 term and three members shall be appointed to a 2-year term.
3 Any vacancy on the advisory council shall be filled in the
4 same manner as the original appointment. All initial
5 appointments shall be made by July 15, 2007. The first meeting
6 shall take place no later than August 15, 2007. All meetings
7 are subject to the call of the chair. Members shall meet at
8 least twice a year or as often as necessary to discharge their
9 duties but shall have no more than four meetings during any
10 12-month period. Members shall serve without compensation but
11 may be reimbursed for per diem and travel expenses in
12 accordance with s. 112.061, subject to a specific
13 appropriation in the General Appropriations Act.

14 (b) The advisory council shall:

15 1. Develop a donated funds program for recommendation
16 to the Secretary of Health to encourage the development of
17 funds other than state appropriations for human adult,
18 amniotic, cord blood, and placental stem cell research in the
19 state.

20 2. Examine and identify specific ways to improve and
21 promote for-profit and not-for-profit human adult, amniotic,
22 cord blood, and placental stem cell and related research in
23 the state, including, but not limited to, identifying both
24 public and private funding sources for such research,
25 maintaining existing human adult, amniotic, cord blood, and
26 placental stem cell-related businesses, recruiting new human
27 adult, amniotic, cord blood, and placental stem cell-related
28 businesses to the state, and recruiting scientists and
29 researchers in such fields to the state and state
30 universities.

31

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

6 4. Develop, no later than September 15, 2007, an
7 application for grants-in-aid under this section for
8 recommendation to the Secretary of Health for the purpose of
9 conducting human adult, amniotic, cord blood, and placental
10 stem cell research.

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

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

16 7. Review all stem cell research that is funded or
17 supported in any manner through the Biomedical Research Trust
18 Fund to ensure the adherence to ethical and safety guidelines
19 and procedures as set forth by federal ethical standards
20 established by the United States Department of Health and
21 Human Services.

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

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

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

31

1 3. The current status and progress of stem cell
2 research in the state.

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

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

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

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

13 8. All other materials the advisory council deems
14 advisable to include.

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

18 (e) The Department of Health shall provide
19 administrative staff to assist the advisory council in
20 developing the application for the grants-in-aid, reviewing
21 the applications, preparing the written consent form described
22 in paragraph (5)(b), and performing other administrative
23 functions as the advisory council requires.

24 (4) BIOMEDICAL RESEARCH TRUST FUND AND
25 GRANTS-IN-AID.--

26 (a) The Secretary of Health shall make grants-in-aid
27 from the Biomedical Research Trust Fund in accordance with the
28 provisions of this section, subject to a specific
29 appropriation in the General Appropriations Act.

30 (b) The Department of Health shall require any
31 applicant for a grant-in-aid under this section, for the

1 purpose of conducting stem cell research, to submit a complete
2 description of the applicant's organization, the applicant's
3 plans for stem cell research, the applicant's proposed funding
4 for such research from sources other than the state, and the
5 applicant's proposed arrangements concerning financial
6 benefits to the state as a result of any patent, royalty
7 payment, or similar right resulting from any stem cell
8 research made possible by the awarding of the grant-in-aid.
9 The advisory council shall provide recommendation to the
10 Secretary of Health with respect to awarding such
11 grants-in-aid.

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

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

15 1. Human adult stem cells. Funding for research may be
16 given for human adult stem cells derived from postmortem
17 tissues, other than from medically induced abortions. Funds
18 may be used for studies of human adult stem cells obtained
19 from either normal or transformed tissues.

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

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

24 4. Placental stem cells extracted from a human
25 placenta that are otherwise discarded after birth.

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

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

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

4 Section 2. Paragraph (h) of subsection (1) of section
5 20.435, Florida Statutes, is amended to read:

6 20.435 Department of Health; trust funds.--

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

9 (h) Biomedical Research Trust Fund.

10 1. Funds to be credited to the trust fund shall
11 consist of funds deposited pursuant to ss. s. 215.5601,
12 288.955, and 381.99 and any other funds appropriated by the
13 Legislature. Funds shall be used for the purposes of the James
14 and Esther King Biomedical Research Program, ~~and~~ the William
15 G. "Bill" Bankhead, Jr., and David Coley Cancer Research
16 Program, and the Florida Hope Offered through Principled,
17 Ethically Sound Stem Cell Research Act as specified in ss.
18 215.5602, 288.955, ~~and~~ 381.922, and 381.99. The trust fund is
19 exempt from the service charges imposed by s. 215.20.

20 2. Notwithstanding the provisions of s. 216.301 and
21 pursuant to s. 216.351, any balance in the trust fund at the
22 end of any fiscal year shall remain in the trust fund at the
23 end of the year and shall be available for carrying out the
24 purposes of the trust fund. The department may invest these
25 funds independently through the Chief Financial Officer or may
26 negotiate a trust agreement with the State Board of
27 Administration for the investment management of any balance in
28 the trust fund.

29 3. Notwithstanding s. 216.301 and pursuant to s.
30 216.351, any balance of any appropriation from the Biomedical
31 Research Trust Fund which is not disbursed but which is

1 obligated pursuant to contract or committed to be expended may
2 be carried forward for up to 3 years following the effective
3 date of the original appropriation.

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

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

8 381.86 Institutional Review Board.--

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

17 Section 4. (1) The Department of Health shall prepare
18 an educational publication, subject to a specific
19 appropriation in the General Appropriations Act, that includes
20 objective information regarding:

21 (a) The medical processes involved in the collection
22 of umbilical cord blood;

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

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

28 1. Discarding the stem cells;

29 2. Donating the stem cells to a public umbilical cord
30 blood bank;

31

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

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

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

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

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

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

18 (h) The average cost of public and private umbilical
19 cord blood banking.

20 (2) The department shall update the publication as
21 necessary.

22 (3) The department shall distribute the publication
23 free of charge to physicians and health care institutions on
24 request and shall make the publication available on its
25 website in a printable format.

26 (4) The department shall encourage health and maternal
27 care professionals providing health care services to a
28 pregnant woman, when those health care services are directly
29 related to her pregnancy, to provide the pregnant woman with
30 the publication by the end of her second trimester.

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

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31

STATEMENT OF SUBSTANTIAL CHANGES CONTAINED IN
COMMITTEE SUBSTITUTE FOR
CS/SB 2496

This committee substitute is different from the committee substitute as filed in the following ways:

- Removes both the \$20 million appropriation for 2006-2007 and the recurring \$20 million appropriation;
- Combines the Research Advisory Council and the Biomedical Ethics Advisory Council into the Stem Cell Research and Ethics Advisory Council;
- Requires that any cell material donated for research must be done with the donor's consent; and
- Limits the use of funds in this section for research conducted at Florida facilities.