

A BILL TO BE ENTITLED

AN ACT

relating to the establishment of an adult stem cell research program and to certain reporting requirements with regard to research involving human stem cells or human cloning.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subtitle H, Title 3, Education Code, is amended by adding Chapter 156 to read as follows:

CHAPTER 156. ADULT STEM CELL RESEARCH PROGRAM

Sec. 156.001. DEFINITIONS. In this chapter:

(1) "Adult stem cell" means an undifferentiated cell that is:

(A) found among differentiated cells in tissues or fluids; and

(B) able to renew itself and differentiate to yield all or nearly all of the specialized cell types needed for clinical applications.

(2) "Advisory committee" means the advisory committee appointed under Section 156.006.

(3) "Consortium" means the Texas Adult Stem Cell Research Consortium.

(4) "Coordinating board" means the Texas Higher Education Coordinating Board.

(5) "Institution of higher education" means an institution of higher education as defined by Section 61.003 or a

1 private college or university that receives state funds.

2 (6) "Multi-institutional, multi-investigator
3 research project" means a research project conducted by two or more
4 cooperating members of the consortium involving one or more
5 researchers from each member of the consortium conducting the
6 research project.

7 (7) "Program" means the adult stem cell research
8 program established under this chapter.

9 (8) "Research oversight committee" means the Texas
10 Adult Stem Cell Research Oversight Committee.

11 Sec. 156.002. PURPOSE. The Texas Adult Stem Cell Research
12 Consortium is established to create and expedite innovation in the
13 area of adult stem cell research and to enhance the potential for a
14 medical or scientific breakthrough in treatment for diseases or
15 disorders.

16 Sec. 156.003. COMPOSITION OF RESEARCH OVERSIGHT COMMITTEE.

17 (a) The research oversight committee is composed of:

18 (1) two members representing the coordinating board,
19 each of whom is appointed by the commissioner of higher education;

20 (2) two members representing the Health and Human
21 Services Commission, each of whom is appointed by the executive
22 commissioner of the Health and Human Services Commission;

23 (3) one member who is an interested person appointed
24 by the governor; and

25 (4) seven professional members with special training
26 and interest in:

27 (A) adult stem cell research;

1 (B) clinical applications involving adult stem
2 cells; or

3 (C) commercialization of products or technology
4 involving adult stem cell research and treatments.

5 (b) The governor shall appoint five of the professional
6 members, two of whom must be selected from a list of candidates
7 prepared by the speaker of the house of representatives, and the
8 lieutenant governor shall appoint two of the professional members.

9 (c) The governor shall designate a member of the research
10 oversight committee as the presiding officer of the research
11 oversight committee. The presiding officer serves in that capacity
12 at the will of the governor.

13 (d) The members of the research oversight committee serve
14 staggered six-year terms, with four members' terms expiring
15 February 1 of each odd-numbered year. If a vacancy occurs on the
16 research oversight committee, the appropriate appointing authority
17 shall appoint, in the same manner as the original appointment,
18 another person to serve for the remainder of the unexpired term.

19 (e) A research oversight committee member is not entitled to
20 compensation but is entitled to reimbursement for necessary
21 expenses, including travel expenses, incurred in performing the
22 duties of a research oversight committee member.

23 Sec. 156.004. CONFLICT OF INTEREST. (a) In this section,
24 "Texas trade association" means a cooperative and voluntarily
25 joined association of business or professional competitors in this
26 state designed to assist its members and its industry or profession
27 in dealing with mutual business or professional problems and in

1 promoting their common interest.

2 (b) A person may not be a member of the research oversight
3 committee if:

4 (1) the person is an officer, employee, or paid
5 consultant of a Texas trade association in the field of medicine; or

6 (2) the person's spouse is an officer, manager, or paid
7 consultant of a Texas trade association in the field of medicine.

8 (c) A person may not be a member of the research oversight
9 committee if the person is required to register as a lobbyist under
10 Chapter 305, Government Code, because of the person's activities
11 for compensation on behalf of a profession related to the operation
12 of the research oversight committee.

13 Sec. 156.005. COMPOSITION OF CONSORTIUM. (a) The research
14 oversight committee shall establish the Texas Adult Stem Cell
15 Research Consortium.

16 (b) The consortium is composed of:

17 (1) participating institutions of higher education
18 that:

19 (A) accept public money for adult stem cell
20 research; or

21 (B) otherwise agree to participate in the
22 consortium;

23 (2) nonprofit entities that conduct adult stem cell
24 research in affiliation with an institution of higher education
25 and:

26 (A) accept public money for adult stem cell
27 research; or

1 (B) otherwise agree to participate in the
2 consortium; and

3 (3) the following umbilical cord blood banks:

4 (A) the Texas Cord Blood Bank;

5 (B) the M. D. Anderson Cord Blood Bank; and

6 (C) any not-for-profit umbilical cord blood bank
7 operating in this state that:

8 (i) stores umbilical cord blood for public
9 use; and

10 (ii) agrees to participate in the
11 consortium.

12 Sec. 156.006. ADVISORY COMMITTEE. (a) An advisory
13 committee is established to make recommendations based on
14 prevailing international best practices in adult stem cell research
15 to assist the research oversight committee in performing its
16 duties. The research oversight committee shall consult with the
17 advisory committee to develop grant and loan application procedures
18 for research proposals submitted by consortium participants.

19 (b) The advisory committee is composed of:

20 (1) a member representing each institution of higher
21 education participating in the consortium, appointed by the
22 president of the institution;

23 (2) a member representing each nonprofit entity
24 participating in the consortium, appointed by the director of the
25 nonprofit entity; and

26 (3) a member representing each umbilical cord blood
27 bank participating in the consortium, appointed by the chief

1 executive officer of the bank.

2 (c) A member of the advisory committee is not entitled to
3 compensation and is not entitled to reimbursement for expenses.

4 (d) Chapter 2110, Government Code, does not apply to the
5 advisory committee.

6 Sec. 156.007. PEER REVIEW PROCEDURES AND CRITERIA.

7 (a) The advisory committee shall establish procedures and
8 criteria for peer review of applications for grants and loans for
9 proposed research projects consistent with national and
10 international standards, including the enhanced review criteria
11 for the evaluation of research applications received for potential
12 funding in fiscal year 2010 and the associated scoring procedures
13 used by the National Institutes of Health. The advisory committee
14 shall establish conflict of interest standards regarding peer
15 reviewers consistent with 42 C.F.R. Section 52h.5.

16 (b) The advisory committee shall select reviewers for the
17 peer review process based on a reviewer's training and experience
18 in relevant scientific, medical, or technical fields, taking into
19 account:

20 (1) the formal scientific or technical education
21 completed;

22 (2) relevant research engaged in by the person,
23 including whether the person was the principal researcher;

24 (3) any awards, honors, or other recognition received
25 from scientific, professional, and medical organizations; and

26 (4) the need to include experts from various areas of
27 specialization within relevant scientific, medical, or technical

1 fields.

2 (c) Notwithstanding Subsection (b), not more than 50
3 percent of the peer reviewers for an application may be residents of
4 this state.

5 (d) A peer reviewer is not an officer or employee of this
6 state.

7 Sec. 156.008. ADMINISTRATION OF PROGRAM; GUIDELINES AND
8 PROCEDURES. (a) The research oversight committee shall
9 administer the program to:

10 (1) make grants and loans on a competitive, peer
11 review basis to consortium participants for:

12 (A) multi-institutional, multi-investigator
13 research projects involving adult stem cells, including projects to
14 develop therapies, protocols, or medical procedures involving
15 adult stem cells; and

16 (B) the commercialization of products or
17 technology involving adult stem cell research and treatments;

18 (2) support consortium participants in all stages of
19 the process of developing treatments and cures based on adult stem
20 cell research, beginning with initial laboratory research through
21 successful clinical trials; and

22 (3) establish appropriate regulatory standards and
23 oversight bodies for adult stem cell research conducted by
24 consortium participants.

25 (b) The research oversight committee shall refer all grant
26 and loan applications to the advisory committee for competitive,
27 peer review evaluation of the medical, scientific, and technical

1 merits of the proposed research project. The advisory committee
2 shall, giving consideration to the substance and results of peer
3 review of individual research project proposals, recommend to the
4 research oversight committee acceptance or rejection of an
5 individual grant or loan application.

6 (c) Money awarded under this chapter may not be used for
7 research using stem cells obtained after an induced abortion.

8 (d) The research oversight committee shall follow the
9 recommendations of the advisory committee in performing its duties.
10 If the research oversight committee does not carry out a
11 recommendation of the advisory committee, the research oversight
12 committee shall provide a reason to the advisory committee in
13 writing not later than the 14th day after the date of the decision
14 and include the reason in its biennial report.

15 Sec. 156.009. FUNDING; SUPPORT. (a) The program may be
16 funded by:

17 (1) gifts, grants, or donations described by Section
18 156.010.

19 (b) The coordinating board shall provide administrative
20 support and resources necessary for the research oversight
21 committee to perform its duties under this chapter.

22 Sec. 156.010. GIFTS AND GRANTS. The consortium shall
23 solicit, and the research oversight committee may accept on behalf
24 of the consortium, a gift, grant, or donation made from any public
25 or private source for the purpose of promoting adult stem cell
26 commercialization or multi-institutional, multi-investigator
27 research projects.

1 Sec. 156.011. BIENNIAL REPORT. Not later than September 1
2 of each even-numbered year, the research oversight committee shall
3 submit a report of the research oversight committee's activities
4 and recommendations to the coordinating board and to the governor,
5 the lieutenant governor, the speaker of the house of
6 representatives, and the presiding officer of each legislative
7 standing committee or subcommittee with jurisdiction over higher
8 education.

9 SECTION 2. Subtitle H, Title 2, Health and Safety Code, is
10 amended by adding Chapter 172 to read as follows:

11 CHAPTER 172. BIOMEDICAL RESEARCH

12 Sec. 172.001. DEFINITION. In this chapter, "state agency"
13 means a department, commission, board, office, or other agency in
14 the executive branch of state government created by the state
15 constitution or a state statute, including an institution of higher
16 education as defined by Section 61.003, Education Code.

17 Sec. 172.002. ANNUAL REPORT. (a) Not later than December
18 1 of each year, a state agency that conducts, funds, or supports
19 biomedical research shall submit to the governor, the Legislative
20 Budget Board, and the commissioner of state health services a
21 report, in the format established by the commissioner, on whether
22 the agency conducted, funded, or supported during the preceding
23 state fiscal year any research that involves human stem cells or
24 human cloning.

25 (b) A state agency that conducts, funds, or supports any
26 research that involves human stem cells or human cloning must
27 include in the report submitted under Subsection (a) information

1 on:

2 (1) the type of research conducted, funded, or
3 supported by the state agency that involves:

4 (A) human stem cells; and

5 (B) human cloning, including therapeutic and
6 reproductive cloning;

7 (2) the process through which the human stem cells and
8 stem cell lines were derived, if applicable;

9 (3) the amount and source of state and federal money,
10 private grants, and other funding used to conduct, fund, or support
11 the research;

12 (4) the use of state facilities to conduct or support
13 the research; and

14 (5) the goals, progress, and results of the research.

15 (c) A state agency shall not include in the report:

16 (1) proprietary, competitive, and other information
17 that the agency is not required to publicly disclose under Chapter
18 552, Government Code; or

19 (2) the name, address, or other personal identifying
20 information of an individual conducting or otherwise participating
21 in research that is the subject of the report.

22 SECTION 3. Not later than December 1, 2009, a state agency
23 that conducts, funds, or supports biomedical research shall submit
24 the initial report required under Chapter 172, Health and Safety
25 Code, as added by this Act.

26 SECTION 4. (a) As soon as possible after the effective
27 date of this Act, the governor, lieutenant governor, executive

1 commissioner of the Health and Human Services Commission, and
2 commissioner of higher education shall appoint members to the Texas
3 Adult Stem Cell Research Oversight Committee in accordance with
4 Chapter 156, Education Code, as added by this Act.

5 (b) In making initial appointments to the Texas Adult Stem
6 Cell Research Oversight Committee:

7 (1) the governor shall appoint:

8 (A) two members to serve a term expiring February
9 1, 2011, one member to serve a term expiring February 1, 2013, and
10 one member to serve a term expiring February 1, 2015; and

11 (B) from a list of candidates prepared by the
12 speaker of the house of representatives, one member to serve a term
13 expiring February 1, 2011, and one member to serve a term expiring
14 February 1, 2015;

15 (2) the lieutenant governor shall appoint one member
16 to serve a term expiring February 1, 2011, and one member to serve a
17 term expiring February 1, 2013;

18 (3) the executive commissioner of the Health and Human
19 Services Commission shall appoint one member to serve a term
20 expiring February 1, 2013, and one member to serve a term expiring
21 February 1, 2015; and

22 (4) the commissioner of higher education shall appoint
23 one member to serve a term expiring February 1, 2013, and one member
24 to serve a term expiring February 1, 2015.

25 SECTION 5. Not later than September 1, 2010, the Texas Adult
26 Stem Cell Research Oversight Committee shall submit the first
27 report of the committee's activities and recommendations as

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1 required by Chapter 156, Education Code, as added by this Act.

2 SECTION 6. This Act takes effect September 1, 2009.