By: Thompson H.B. No. 537

A BILL TO BE ENTITLED

1	AN ACT
2	relating to research using human cells and tissues.
3	BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:
4	SECTION 1. Subtitle H, Title 2, Health and Safety Code, is
5	amended by adding Chapter 172 to read as follows:
6	CHAPTER 172. TEXAS INSTITUTE FOR REGENERATIVE MEDICINE
7	Sec. 172.001. DEFINITIONS. In this chapter:
8	(1) "Committee" means the Independent Citizens
9	Oversight Committee established by Section 172.002.
LO	(2) "Financial accountability oversight committee"
L1	means the financial accountability oversight committee established
L2	by Section 172.009.
L3	(3) "Institute" means the Texas Institute for
L4	Regenerative Medicine established by Section 73, Article XVI, Texas
L5	Constitution.
L6	Sec. 172.002. INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE.
L7	(a) The committee is the governing body of the institute.
L8	(b) The committee is composed of nine members appointed as
L9	<u>follows:</u>
20	(1) one member appointed by the chancellor of The
21	University of Texas System to represent:
22	(A) The University of Texas Medical Branch at
23	<pre>Galveston;</pre>

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(B) The University of Texas at San Antonio;

1	(C) The University of Texas at Dallas; or
2	(D) The University of Texas Health Science
3	<pre>Center;</pre>
4	(2) one member appointed by the governor to represent:
5	(A) The Texas A&M University System;
6	(B) the Texas Tech University System;
7	(C) the University of Houston System;
8	(D) the Texas State University System; or
9	(E) the University of North Texas System;
10	(3) two members appointed by the governor, one of whom
11	must be selected from a list submitted by the speaker of the house
12	of representatives, one member appointed by the lieutenant
13	governor, and one member appointed by the comptroller from any of
14	the following categories:
15	(A) a representative of a university in this
16	state other than the universities listed in Subdivisions (1) and
17	(2) that has demonstrated success and leadership in regenerative
18	<pre>medical research and that has:</pre>
19	(i) a research hospital and medical school;
20	(ii) a recent proven history of
21	administering scientific or medical research grants or contracts in
22	an average annual range of more than \$20 million; and
23	(iii) a ranking, in the past five years, in
24	the top 50 universities in the United States with the highest number
25	of life science patents or that has research or clinical faculty who
26	are members of the National Academy of Sciences;
27	(B) a representative from a nonprofit academic

1	and research institution in this state that is not a part of The
2	University of Texas System that has:
3	(i) demonstrated success and leadership in
4	stem cell research; and
5	(ii) a nationally ranked research hospital
6	or research or clinical faculty who are members of the National
7	Academy of Sciences;
8	(C) a resident of this state who has a background
9	in medical ethics; and
10	(D) a resident of this state with a background in
11	finance; and
12	(4) two members appointed by the governor, one of whom
13	must be selected from a list submitted by the speaker of the house
14	of representatives, and one member appointed by the lieutenant
15	governor to represent a disease advocacy group, which may include
16	an advocacy group for any of the following diseases:
17	(A) spinal cord injury;
18	(B) Alzheimer's disease;
19	(C) diabetes;
20	(D) multiple sclerosis;
21	(E) amyotropic lateral sclerosis;
22	(F) HIV or AIDS;
23	(G) mental health diseases;
24	(H) heart disease;
25	(I) cancer; or
26	(J) Parkinson's disease.
27	Sec. 172.003. OFFICERS. (a) The committee shall elect from

- 1 among its members a presiding officer and an assistant presiding
- 2 officer.
- 3 (b) The officers serve a term of three years and shall be
- 4 part-time or full-time employees of the institute.
- 5 (c) The presiding officer:
- 6 (1) must have been appointed under Section
- 7 172.002(b)(3) or (4) and have the following qualifications:
- 8 (A) documented history in successful stem cell
- 9 research advocacy; and
- 10 (B) experience with state and federal
- 11 legislative processes, including experience with medical
- 12 legislative approvals of standards or funding; and
- 13 (2) may not concurrently be employed by or on leave
- 14 from an institution that seeks or receives state grants or loans.
- 15 (d) In electing a presiding officer the committee may also
- 16 <u>consider:</u>
- 17 <u>(1) executive experience with governmental agencies</u>
- 18 or institutions;
- 19 (2) experience with the process of establishing
- 20 government standards and procedures;
- 21 (3) experience with the legal review of proper
- 22 governmental authority for the exercise of government agency or
- 23 government institutional powers; and
- 24 (4) direct knowledge and experience in bond financing.
- 25 (e) The assistant presiding officer must:
- 26 (1) meet the requirements of Subsections (c)(1)(A) and
- 27 (2); and

- 1 (2) have attributes and experience complementary to
- 2 those of the presiding officer, preferably meeting criteria not met
- 3 by the presiding officer's credentials and experience.
- 4 Sec. 172.004. TERMS. (a) Committee members serve
- 5 staggered six-year terms, with as near as possible to one-third of
- 6 the members' terms expiring on February 1 of each odd-numbered
- 7 year.
- 8 (b) A committee member may not serve more than one term.
- 9 (c) If a vacancy occurs on the committee during a term, the
- 10 appointing authority shall appoint a successor to serve for the
- 11 unexpired portion of the term not later than 30 days after the
- 12 vacancy occurs.
- 13 (d) On the expiration of a committee member's term, the
- 14 appointing authority must make a replacement appointment not later
- than 30 days after the date that a term expires. The member whose
- 16 term expires continues to serve on the committee until a
- 17 replacement is made.
- 18 Sec. 172.005. POWERS AND DUTIES. The institute has the
- 19 powers conferred under Section 73, Article XVI, Texas Constitution.
- Sec. 172.006. STEM CELL RESEARCH ACCOUNT. The stem cell
- 21 research account is an account in the general revenue fund. The
- 22 account may be used only as provided by Section 73, Article XVI,
- 23 Texas Constitution.
- Sec. 172.007. ANNUAL PUBLIC REPORT. The institute shall
- 25 issue an annual public report outlining the institute's activities,
- grants awarded, grants in progress, research accomplishments, and
- 27 future program directions. The report should include:

1	(1) the number and dollar amounts of research and
2	<pre>facilities grants;</pre>
3	(2) identification of the grantees for the reported
4	<pre>year;</pre>
5	(3) the institute's administrative expenses;
6	(4) an assessment of the availability of funding for
7	stem cell research from sources other than the institute;
8	(5) a summary of research findings, including
9	promising new research areas;
10	(6) an assessment of the relationship between the
11	institute's grants and the overall strategy of its research
12	program; and
13	(7) a report of the institute's strategic research and
14	financial plans.
15	Sec. 172.008. INDEPENDENT FINANCIAL AUDIT FOR REVIEW BY
16	COMPTROLLER. The institute shall annually commission ar
17	independent financial audit of its activities from a certified
18	public accounting firm that shall be provided to the comptroller,
19	who shall review the audit and annually issue a public report of
20	that review.
21	Sec. 172.009. FINANCIAL ACCOUNTABILITY OVERSIGHT
22	COMMITTEE. (a) The comptroller shall be the presiding officer of a
23	financial accountability oversight committee that:
24	(1) reviews the annual financial audit, the
25	comptroller's report and evaluation of that audit, and the
26	financial practices of the institute; and

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(2) provides recommendations on the institute's

- 1 <u>financial practices and performance.</u>
- 2 (b) The governor shall appoint one public member of the
- 3 financial accountability oversight committee from a list submitted
- 4 by the speaker of the house of representatives. The lieutenant
- 5 governor, the comptroller, and the presiding officer of the
- 6 committee shall each appoint a public member of the financial
- 7 accountability oversight committee. Financial accountability
- 8 oversight committee members must have medical backgrounds and
- 9 knowledge of relevant financial matters.
- 10 (c) The comptroller shall provide staff support for the
- 11 <u>financial accountability oversight committee.</u>
- 12 (d) The financial accountability oversight committee shall
- 13 hold an annual public meeting, with appropriate notice and with a
- 14 formal public comment period. The committee shall evaluate public
- 15 comments and include appropriate summaries in its annual report.
- 16 (e) The committee shall provide funds for the per diem
- 17 expenses of the financial accountability oversight committee
- 18 members and for publication of the annual report.
- 19 SECTION 2. Subtitle H, Title 2, Health and Safety Code, is
- amended by adding Chapter 173 to read as follows:
- 21 CHAPTER 173. RESEARCH USING HUMAN CELLS AND TISSUE
- 22 Sec. 173.001. USE OF HUMAN CELLS PERMITTED. (a) A person
- 23 may conduct research involving the derivation and use of human
- 24 embryonic stem cells, human embryonic germ cells, and human adult
- 25 stem cells, including somatic cell nuclear transplantation.
- 26 (b) The research authorized by this section:
- 27 (1) must be conducted with full consideration for the

H.B. No. 537 ethical and medical implications of the research; and 1 2 (2) must be reviewed by an institutional review board. Sec. 173.002. DUTY OF HEALTH CARE PROVIDER. A physician or 3 other health care provider who is delivering fertility treatment 4 shall provide the patient with timely, relevant, and appropriate 5 6 information sufficient to allow the patient to make an informed and 7 voluntary choice regarding the disposition of any human embryos 8 remaining following the infertility treatment in accordance with 9 Section 173.003. Sec. 173.003. PATIENT OPTIONS. (a) The information given 10 to the patient under Section 173.002 must inform the patient of the 11 12 patient's options to: 13 (1) store any unused embryos; 14 (2) donate the unused embryos to another person for 15 use; (3) <u>discard the unused embryos; or</u> 16 17 (4) donate the unused embryos for research purposes. (b) A patient who donates, for research purposes, embryos 18 19 remaining after infertility treatment must consent in writing to 20 the donation. 21 SECTION 3. Section 48.02(c), Penal Code, is amended to read as follows: 22

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that the valuable consideration is: (1) a fee paid to a physician or

to other medical personnel for services rendered in the usual

course of medical practice or a fee paid for hospital or other

clinical services; (2) reimbursement of legal or medical expenses

(c) It is an exception to the application of this section

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- 1 incurred for the benefit of the ultimate receiver of the organ; (3)
- 2 reasonable payment for removal, processing, disposal,
- 3 preservation, quality control, storage, transplantation, or
- 4 implantation of embryonic or cadaveric fetal tissue for research
- 5 conducted in compliance with Chapter 173, Health and Safety Code;
- 6 or (4) [(3)] reimbursement of expenses of travel, housing, and
- 7 lost wages incurred by the donor of a human organ in connection with
- 8 the donation of the organ.
- 9 SECTION 4. (a) Subject to Section 6(b) of this Act, not
- 10 later than December 1, 2007, the chancellor of The University of
- 11 Texas System, the governor, the lieutenant governor, and the
- 12 comptroller of public accounts shall appoint members to the
- 13 Independent Citizens' Oversight Committee as required by Section
- 14 172.002, Health and Safety Code, as added by this Act.
- 15 (b) Subject to Section 6(b) of this Act, not later than
- January 1, 2008, the members of the Independent Citizens' Oversight
- 17 Committee shall elect a presiding officer and assistant presiding
- officer as required by Section 172.003, Health and Safety Code, as
- 19 added by this Act.
- 20 SECTION 5. (a) The change in law made by this Act to Section
- 48.02(c), Penal Code, applies only to an offense committed on or
- 22 after the effective date of this Act. For purposes of this section,
- 23 an offense is committed before the effective date of this Act if any
- 24 element of the offense occurs before that date.
- 25 (b) An offense committed before the effective date of this
- 26 Act is covered by the law in effect when the offense was committed,
- 27 and the former law is continued in effect for that purpose.

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- SECTION 6. (a) Except as provided by Subsection (b), this
 Act takes effect September 1, 2007.
- 3 (b) Section 1 of this Act takes effect on the date on which 4 the constitutional amendment proposed by the 80th Legislature, 5 Regular Session, 2007, establishing the Texas Institute for 6 Regenerative Medicine and prohibiting the legislature from 7 prohibiting stem cell research is approved by the voters. If that 8 amendment is not approved by the voters, Section 1 of this Act has 9 no effect.