

By: Watson

S.B. No. 2030

A BILL TO BE ENTITLED

AN ACT

relating to the regulation of certain research.

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

SECTION 1. Subtitle G, Title 10, Government Code, is amended by adding Chapter 2312 to read as follows:

CHAPTER 2312. REGULATION OF CERTAIN RESEARCH

Sec. 2312.001. DEFINITIONS. In this chapter:

(1) "Institutional review board" includes an independent ethics committee or ethical review board designated to approve research by the United States Department of Health and Human Services, the United States Food and Drug Administration, or any other federal agency or entity.

(2) "Permit" means a license, certificate, approval, registration, consent, permit, contract, or other agreement related to conducting research in this state or other form of authorization required by law, rule, order, or ordinance that a person must obtain from a regulatory agency to conduct research in this state or initiate, continue, or complete a project for which a permit is sought.

(3) "Project" means research over which a regulatory agency exerts its jurisdiction and for which one or more permits are required to initiate, continue, or complete the research.

(4) "Regulatory agency" means this state or a political subdivision of this state and includes a bureau,

1 department, division, board, commission, or other agency of this  
2 state or the governing body of that entity.

3 (5) "Research" means a scientific endeavor for which  
4 approval by an institutional review board is required.

5 Sec. 2312.002. APPLICABILITY OF CHAPTER. This chapter  
6 applies only to a project conducted through:

7 (1) a public or private institution of higher  
8 education in this state; or

9 (2) a business entity authorized to engage in business  
10 in this state.

11 Sec. 2312.003. DATE OF VESTING OF PROJECT. (a) Subject to  
12 Subsection (b), a project vests on the date an institutional review  
13 board issues an initial approval of a project.

14 (b) A project for which an institutional review board issues  
15 an initial approval before September 1, 2009, vests on September 1,  
16 2009.

17 Sec. 2312.004. EFFECT OF VESTING. When a project is vested,  
18 an applicant for a permit from a regulatory agency in relation to  
19 the project is entitled to the rights described by this chapter.

20 Sec. 2312.005. ENTITLEMENT TO UNIFORMITY OF REQUIREMENTS.  
21 An applicant for a permit from a regulatory agency for a project  
22 vested as provided by Section 2312.003, including a permit for a  
23 part of the project, is entitled to have the regulatory agency  
24 consider the approval, disapproval, or conditional approval of the  
25 permit solely on the basis of any order, ordinance, rule,  
26 expiration date, or other properly adopted requirement in effect on  
27 the date the project vested.

1       Sec. 2312.006. ENTITLEMENT APPLIES TO SUBSEQUENT RESEARCH  
2 AND COMMERCIALIZATION. The right described by Section 2312.005 in  
3 relation to a project or a part of a project begins on the date the  
4 project vests and continues:

5           (1) through scientific endeavor subsequent to the  
6 original research, without regard to whether the endeavor requires  
7 approval by an institutional review board, if the endeavor  
8 continues or relates to the purposes of the project; and

9           (2) through commercialization efforts subsequent to  
10 the original research if those efforts continue or relate to the  
11 purposes of the project.

12       Sec. 2312.007. SERIES OF PERMITS. (a) If a series of  
13 permits from a regulatory agency is required for a project, the  
14 order, ordinance, rule, expiration date, or other properly adopted  
15 requirement in effect on the date the original application for the  
16 first permit in that series is filed shall be the sole basis for  
17 consideration of all subsequent permits required for completion of  
18 the project.

19           (b) All permits required for a project from a regulatory  
20 agency are considered to be a single series of permits.

21       Sec. 2312.008. CHANGE IN DURATION. On or after the date  
22 that a project is vested, a regulatory agency may not shorten the  
23 duration of any permit required for the project.

24       Sec. 2312.009. PERMIT CHANGES THAT BENEFIT PROJECT.  
25 Notwithstanding any other provision of this chapter, a permit  
26 holder may take advantage of a change to the law relating to a  
27 regulatory agency or a rule or ordinance of a regulatory agency that

1 benefits, enhances, or protects the project, including changes that  
2 lengthen the effective life of the permit after the date the project  
3 vested, without forfeiting any right under this chapter.

4 Sec. 2312.010. TECHNICAL PERMIT REQUIREMENTS. This chapter  
5 does not prohibit a regulatory agency from requiring compliance  
6 with a technical requirement relating to the form and content of an  
7 application for a permit for a project in effect at the time the  
8 application is filed, even if the application is filed after the  
9 date the project is vested.

10 Sec. 2312.011. EXEMPTIONS. This chapter does not apply to a  
11 change relating to a permit for a project that a regulatory agency  
12 has adopted on or after the date the project vested if the change:

13 (1) is enacted solely to address an imminent threat of  
14 destruction of property or injury to a person; or

15 (2) results in an increased fee for the permit if the  
16 increase is reasonably related to the administrative costs  
17 associated with issuing the permit.

18 Sec. 2312.012. ENFORCEMENT OF CHAPTER. (a) This chapter  
19 may be enforced only through mandamus or declaratory or injunctive  
20 relief.

21 (b) The immunity of a regulatory agency from suit is waived  
22 for an action under this chapter.

23 SECTION 2. This Act applies to a research project without  
24 regard to whether the project began before, on, or after the  
25 effective date of this Act.

26 SECTION 3. This Act takes effect September 1, 2009.