

By: Rodriguez

H.B. No. 1029

A BILL TO BE ENTITLED

AN ACT

relating to approval procedures of institutional review boards for certain clinical trials.

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

SECTION 1. Subtitle A, Title 6, Health and Safety Code, is amended by adding Chapter 442 to read as follows:

CHAPTER 442. INSTITUTIONAL REVIEW BOARD PROCEDURES

Sec. 442.001. DEFINITIONS. In this chapter:

(1) "Clinical drug trial" means a research study in human volunteers designed to evaluate the safety and effectiveness of a drug.

(2) "Institutional review board" means a board, committee, or other group formally designated by an institution or authorized under federal or state law to review or approve the initiation of or conduct periodic review of research programs to ensure the protection of the rights and welfare of human research subjects.

Sec. 442.002. REQUIRED APPROVAL PROCEDURE. An institutional review board may not approve a clinical drug trial unless the person conducting the trial agrees to:

(1) register the clinical drug trial with the National Institutes of Health website for clinical trials; and

(2) publish the results of the clinical drug trial in electronic format on the Internet in a manner readily understood by

1 the public.

2           SECTION 2. The change in law made by this Act applies only  
3 to a clinical drug trial approved on or after the effective date of  
4 this Act. A clinical drug trial approved before the effective date  
5 of this Act is covered by the law in effect when the clinical drug  
6 trial was approved, and the former law is continued in effect for  
7 that purpose.

8           SECTION 3. This Act takes effect September 1, 2005.