



ATTORNEY GENERAL OF TEXAS
GREG ABBOTT

May 11, 2005

Ms. Carol Longoria
Public Information Coordinator
University of Texas System
201 West Seventh Street
Austin, Texas 78701-2902

OR2005-04101

Dear Ms. Longoria:

You ask whether certain information is subject to required public disclosure under the Public Information Act (the "Act"), chapter 552 of the Government Code. Your request was assigned ID# 223913.

The University of Texas M.D. Anderson Cancer Center (the "university") received a request for all written communications dated December 17, 2004 to the present between the university and Pfizer Inc. ("Pfizer") relating to a specified clinical trial. You claim that the submitted information is excepted from disclosure under sections 552.101, 552.104, and 552.110 of the Government Code. You indicate that, pursuant to section 552.305(d) of the Government Code, you notified Pfizer of the request and of its opportunity to submit comments to this office. *See* Gov't Code § 552.305 (permitting interested third party to submit to attorney general reasons why requested information should not be released); Open Records Decision No. 542 (1990) (determining that statutory predecessor to section 552.305 permits governmental body to rely on interested third party to raise and explain applicability of exception to disclosure in certain circumstances). Pfizer has submitted to this office arguments against disclosure of the requested information. We have considered the exceptions you claim and reviewed the submitted information.¹

¹ We assume that the sample of records submitted to this office is truly representative of the requested records as a whole. *See* Open Records Decision Nos. 499 (1988), 497 (1988). This open records letter does not reach, and therefore does not authorize the withholding of, any other requested records to the extent that those records contain substantially different types of information than that submitted to this office.

Section 552.101 excepts from disclosure “information deemed confidential by law, either constitutional, statutory, or by judicial decision” and encompasses information made confidential by other statutes. Gov’t Code § 552.101. Section 161.032(a) makes confidential “records and proceedings of a medical committee.” Section 161.032 provides in part:

(a) The records and proceedings of a medical committee are confidential and are not subject to court subpoena.

....

(c) Records, information, or reports of a medical committee . . . and records, information, or reports provided by a medical committee . . . to the governing body of a public hospital . . . are not subject to disclosure under Chapter 552, Government Code.

....

(f) This section . . . do[es] not apply to records made or maintained in the regular course of business by a . . . university medical center or health science center[.]

Health & Safety Code § 161.0315(a), (c), (f). A “medical committee” includes any committee, including joint committee, of a university medical school or health science center. Health and Safety Code § 161.032(a). Moreover, the term includes “a committee appointed ad hoc to conduct a specific investigation or established under state or federal law or rule or under the bylaws or rules of the organization or institution.” Health & Safety Code § 161.031(b). Section 161.0315 provides in relevant part that the governing body of a university medical school or health science center “may form . . . a medical committee, as defined by section 161.031, to evaluate medical and health care services.” Health & Safety Code § 161.0315(a).

You state that all of the responsive documents are directed to the university’s Institutional Review Board (“IRB”), either directly or via the university’s contact for the clinical trial at issue. You further state that all of the requested documents are medical committee documents utilized by the university’s IRB for purposes of patient safety and quality improvement. An IRB is a committee established pursuant to federal law.² Federal regulations define an IRB as

² See 42 U.S.C. § 289(a) (providing that Secretary of Health and Human Services shall by regulation require that each entity which applies for grant, contract, or cooperative agreement for any project or program which involves conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to Secretary that it has established “Institutional Review Board” to review biomedical and behavioral research involving human subjects conducted at or supported by such entity).

any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects

21 C.F.R § 56.102(g). We conclude that the university's IRB is a medical committee created pursuant to federal law, and consequently, the IRB falls within the definition of "medical committee" set forth in section 161.031 of the Health and Safety Code. Moreover, based upon your representations and our review, we conclude that the submitted documents constitute records of the university's IRB and are confidential under section 161.032. *See Jordan v. Court of Appeals*, 701 S.W.2d 644, 647-48 (Tex. 1985) (determining that statutory predecessor extended to documents prepared by or at direction of committee in order to conduct open and thorough review, and privilege extends to minutes of committee meetings, correspondence between members relating to deliberation process, and any final committee product); *see also* Open Records Decision No. 591 (1991) (concluding that purpose of predecessor statute was to encourage frank discussion by medical professionals). Accordingly, the university must withhold the submitted information under section 552.101 of the Government Code.³

This letter ruling is limited to the particular records at issue in this request and limited to the facts as presented to us; therefore, this ruling must not be relied upon as a previous determination regarding any other records or any other circumstances.

This ruling triggers important deadlines regarding the rights and responsibilities of the governmental body and of the requestor. For example, governmental bodies are prohibited from asking the attorney general to reconsider this ruling. Gov't Code § 552.301(f). If the governmental body wants to challenge this ruling, the governmental body must appeal by filing suit in Travis County within 30 calendar days. *Id.* § 552.324(b). In order to get the full benefit of such an appeal, the governmental body must file suit within 10 calendar days. *Id.* § 552.353(b)(3), (c). If the governmental body does not appeal this ruling and the governmental body does not comply with it, then both the requestor and the attorney general have the right to file suit against the governmental body to enforce this ruling. *Id.* § 552.321(a).

If this ruling requires the governmental body to release all or part of the requested information, the governmental body is responsible for taking the next step. Based on the statute, the attorney general expects that, upon receiving this ruling, the governmental body will either release the public records promptly pursuant to section 552.221(a) of the Government Code or file a lawsuit challenging this ruling pursuant to section 552.324 of the

³ As our ruling on this issue is dispositive, we need not address any of the remaining arguments against disclosure.

Government Code. If the governmental body fails to do one of these things, then the requestor should report that failure to the attorney general's Open Government Hotline, toll free, at (877) 673-6839. The requestor may also file a complaint with the district or county attorney. *Id.* § 552.3215(e).

If this ruling requires or permits the governmental body to withhold all or some of the requested information, the requestor can appeal that decision by suing the governmental body. *Id.* § 552.321(a); *Tex. Dep't of Pub. Safety v. Gilbreath*, 842 S.W.2d 408, 411 (Tex. App.—Austin 1992, no writ).

Please remember that under the Act the release of information triggers certain procedures for costs and charges to the requestor. If records are released in compliance with this ruling, be sure that all charges for the information are at or below the legal amounts. Questions or complaints about over-charging must be directed to Hadassah Schloss at the Texas Building and Procurement Commission at (512) 475-2497.

If the governmental body, the requestor, or any other person has questions or comments about this ruling, they may contact our office. We note that a third party may challenge this ruling by filing suit seeking to withhold information from a requestor. Gov't Code § 552.325. Although there is no statutory deadline for contacting us, the attorney general prefers to receive any comments within 10 calendar days of the date of this ruling.

Sincerely,



Ramsey A. Abarca
Assistant Attorney General
Open Records Division

RAA/jev

Ref: ID# 223913

Enc. Submitted documents

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