



March 8, 2001

Mr. J. Robert Giddings
The University of Texas System
201 West 7th Street
Austin, Texas 78701-2981

OR2001-0912

Dear Mr. Giddings:

You ask whether certain information is subject to required public disclosure under chapter 552 of the Government Code. Your request was assigned ID# 144385.

The University of Texas Medical Branch at Galveston ("UTMB") received two requests from the same requestor for minutes of the Institutional Review Board (the "IRB"). The first request seeks the minutes of the IRB for the month of July, 2000. The second request seeks the minutes of the IRB from January, 1996 to the present. As information responsive to the requestor's first request is encompassed by his second request, and as you raise identical exceptions for withholding the information responsive to both requests, we are consolidating both requests under the identification number listed above.¹ You claim that the requested information is excepted from disclosure under section 552.101 of the Government Code in conjunction with several confidentiality statutes, as well as under section 552.110 of the Government Code. With regard to your section 552.110 claim, you state that you will notify certain third parties of the request for information to enable them to make an argument to this office as to the confidentiality of their proprietary information. *See Gov't Code* § 552.305 (permitting interested third party to submit to attorney general reasons why requested

¹We note that the requestor made his original request for the minutes of the IRB in August of 2000, and we acknowledge the argument by counsel for the requestor that UTMB missed the 10-day deadline for submitting a request for a ruling to this office. We also acknowledge UTMB's argument that the requestor withdrew his August request by operation of law under section 552.2615(b) of the Government Code. Because the requestor made a subsequent request for the identical information sought in his original request in August, and because we find that the requested information is confidential by law, we need not address the merits of these assertions in this ruling. *See Gov't Code* § 552.301, 552.302.

information should not be released); Open Records Decision No. 542 (1990) (determining that statutory predecessor to Gov't Code § 552.305 permits governmental body to rely on interested third party to raise and explain applicability of exception in Open Records Act in certain circumstances). We have received no arguments from third parties. Therefore, we will address your arguments for withholding the requested information. We have considered the exceptions you claim and reviewed the submitted representative sample of information.²

Section 552.101 of the Government Code excepts "information considered to be confidential by law, either constitutional, statutory, or by judicial decision." You assert that "all records generated by the Institutional Review Board" are confidential pursuant to section 552.101 in conjunction with sections 161.031 and 161.032 of the Health and Safety Code. Section 161.032(a) provides in relevant part:

The records and proceedings of a medical committee are confidential and are not subject to court subpoena Records, information, or reports of a medical committee ... are not subject to disclosure under Chapter 552, Government Code.

Section 161.031(a) defines a "medical committee" as "any committee . . . of (3) a university medical school or health science center . . ." Section 161.031(b) provides that the "term includes a committee appointed ad hoc to conduct a specific investigation or *established under state or federal law . . .*" [Emphasis added]. However, the confidentiality does not extend to "records made or maintained in the regular course of business by a . . . university medical center or health science center." Health & Safety Code § 161.032(c).

You inform us that the IRB of UTMB is a university or health science center committee established to oversee and review human research activities pursuant to federal law.³ Federal regulations define an IRB as

²We assume that the "representative 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. In this regard, we also note that as part of your submission of materials to this office, you have included several contracts which are contained in attachment D. As we conclude that these contracts are not responsive to the request for minutes of the IRB, this ruling does not address the public availability of the contracts submitted in attachment D.

³See 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). Thus, we conclude that the IRB of UTMB is a medical committee created under 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.

Next, we consider whether the submitted documents are confidential as the records and proceedings of a medical committee under section 161.032. In interpreting the predecessor to this section, the Texas Supreme Court in *Jordan v. Court of Appeals*, 701 S.W.2d 644, 647- 48 (Tex. 1985), stated that “the statutory language, ‘records and proceedings’ means those documents generated by the committee in order to conduct open and thorough review. In general, this privilege extends to documents that have been prepared by or at the direction of the committee for committee purposes.” The *Jordan* court found that the privilege extends to “minutes of committee meetings, correspondence between members relating to the deliberation process and any final committee product, such as recommendations.” *Jordan*, 701 S.W.2d at 648.

The requestor seeks the minutes of the IRB for a specified time period. Based on our review of the submitted documents, we conclude that these documents are records, information, or reports of a medical committee for the purposes of section 161.032(a) of the Health and Safety Code. Therefore, we find that the submitted minutes of UTMB’s IRB are confidential pursuant to section 552.101 of the Government Code, in conjunction with section 161.032(a) of the Health and Safety Code. Accordingly, UTMB must withhold the requested minutes from public disclosure. *See* Open Records Decision No. 591 (1991) (Texas court decisions construing section 161.032 of Health and Safety Code establish that minutes of a medical committee are confidential; therefore, minutes of hospital’s Quality Management Committee are within scope of confidentiality provision).

We recognize that our interpretation of section 161.032(a) of the Health and Safety Code as it applies to IRB minutes is not in accord with the decisions cited by counsel for the requestor. In *Esdale v. American Community Mutual Insurance Co.*, 1995 WL 263479 (N.D. Ill., May 3, 1995), the court found that the records of the IRB of M.D.Anderson Cancer Center were not protected under section 161.032, stating, “if the Texas legislature had intended to include institutional review boards within the scope of the confidentiality statutes, the legislature would have expressly so provided.” The *Esdale* court further found that federal laws relating to IRB record-keeping preempted state laws in this area, and said “[n]owhere in the federal statute and federal regulations creating institutional review boards is there any provision restricting public access to the records or otherwise designating those records as confidential or privileged.”

The *Esdale* court refers specifically to section 46.115 of title 45 of the Code of Federal Regulations which sets forth record-keeping requirements for IRBs. This regulation provides in pertinent part:

(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

....

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

....

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. *All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.* [Emphasis added]

45 C.F.R. § 46.115(a),(b). In *Konrady v. Oesterling*, 149 F.R.D. 592 (D. Minn. 1993), the court found that the IRB of the Mayo Clinic was not a “review organization” protected by the Minnesota peer review statute because the underlying policy of providing confidentiality to peer review deliberations – to encourage physicians to criticize and review one another in an environment closed to civil litigants pursuing cases against the physician – is not present in the deliberations of IRBs. The *Konrady* court also referred to record-keeping requirements for IRBs, those set forth in section 56.115 of title 21 of the Code of Federal Regulations. These regulations are identical to those set forth above with regard to IRB record-keeping, except that they refer specifically to the Food and Drug Administration, as follows:

(b) The records required by this regulation shall be retained for at least 3 years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Food and Drug Administration at reasonable times and in a reasonable manner.

21 C.F.R. § 56.115(b). We find that these federal court decisions are not binding on this office, and we decline to follow their reasoning. *Cf. Texas Oil & Gas Corp. v. Vela*, 405 SW2d 68, 73-74 (Tex. App. - San Antonio 1966); *rev'd on other grounds*, 429 S.W.2d 866

(Tex. 1968) (decision of Fifth Circuit Court of Appeals not controlling in its interpretation of Texas law but persuasive as only precedent on point in question); *Penrod Drilling Corp. v. Williams*, 868 SW2d 294 (Tex. 1993) (while Texas courts may draw upon precedent of Fifth Circuit, or any other federal or state court, in determining appropriate federal rule of decision, they are obligated to follow only higher Texas courts and U.S. Supreme Court).

Specifically, in contrast to the *Esdale* court, this office does believe the Texas legislature intended to cover entities such as the IRB, which we believe fall squarely within the definition of "medical committee" set forth in sections 161.031(a)(3) and 161.031(b) of the Health and Safety Code. Concerning *Konrady*, we are not persuaded that the court's interpretation of the Minnesota peer review statute at issue in that case, as it applied to IRBs, is controlling with regard to whether the records and proceedings of UTMB's IRB would be considered privileged under section 162.032(a) of the Texas Health and Safety Code. In support, we note that in *Doe v. Illinois Masonic Medical Center*, 297 Ill. App. 3d 240, 696 N.E. 2d 707 (Ill. App. Ct. 1998), the court declined to follow *Konrady*, finding that a hospital's IRB was a committee of a licensed or accredited hospital for purposes of the Illinois Medical Studies Act, and therefore records of the IRB were privileged. The *Masonic* court stated that the fact that "federal law mandates the establishment of an IRB in this experimental type of medical study does not negate the IRB's status as a hospital committee." 297 Ill. App. 3d at 244, 696 N.E. 2d at 710. In addition, the court found that "the case of *Konrady* (citation omitted) which was relied upon by the trial court, is not persuasive, because the Illinois statute is broader than the Minnesota statute construed in *Konrady*, which was expressly limited to peer review and contained no privilege for medical study information as expressly provided for by the Illinois Act." *Id.*

In addition, with regard to whether Texas law is preempted in this area, we note that state law is not preempted by federal legislation unless: (1) congress has indicated its intent to preempt or (2) state law is in conflict with federal law either by frustrating congress' purpose or because compliance with both state and federal law is impossible. See *Zachry-Dillingham v. American President Lines, Ltd.*, 739 S.W. 2d 420 (Tex. App.- San Antonio 1987, writ den). We have not been shown that federal law preempts Texas law with regard to the confidentiality of the requested information.

We finally note the argument by counsel for the requestor that the requested minutes of the IRB are public records under a provision of the Texas Open Meetings Act ("TOMA"), section 551.001 *et. seq.* of the Government Code. Section 551.022 of the Government Code provides that "[t]he minutes and tape recordings of an open meeting are public records and shall be available for public inspection and copying on request" Whether the IRB is in fact a governmental body for purposes of the TOMA, and whether the requested minutes of meetings of the IRB from January 1996 to the present are public because those meetings were in fact required to be held in the open, are determinations this office cannot make. See Open Records Decision No. 495 (1988) (attorney general lacks general statutory authority to "enforce" TOMA, and addresses questions arising under TOMA only under general

constitutional and statutory authority authorizing attorney general to issue legal opinions; even in an opinion to authorized requestor, attorney general cannot resolve disputed fact questions such as whether particular meeting actually complied with TOMA). We do note, however, that section 161.032(a) of the Health and Safety Code provides that “a proceeding of a medical peer review committee, as defined by Section 1.03, Medical Practice Act (Article 4495b, Vernon's Texas Civil Statutes), or medical committee, or a meeting of the governing body of a public hospital, hospital district, or hospital authority at which the governing body receives records, information, or reports provided by a medical committee or medical peer review committee is not subject to” TOMA.

To summarize, we find that the requested information is confidential pursuant to section 161.032(a) of the Health and Safety Code, and therefore must be withheld under section 552.101 of the Government Code.⁴

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, within 10 calendar days of this ruling, the governmental body will do one of the following three things: 1) release the public records; 2) notify the requestor of the exact day, time, and place that copies of the records will be provided or that the records can be inspected; or 3) notify the requestor of the governmental body's intent to challenge this letter ruling in court. If the governmental body fails to do one of these three things within 10 calendar days of this ruling, 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).

⁴As we resolve your request for this information under section 552.101, we need not address your other raised exceptions to disclosure.

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); *Texas Department of Public 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 General Services 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. 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,



Michael A. Pearle
Assistant Attorney General
Open Records Division

MAP/seg

Ref: ID# 144385

Encl. Submitted documents

cc: Mr. Mike Ward
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(w/o enclosures)