



ATTORNEY GENERAL OF TEXAS  
GREG ABBOTT

June 28, 2013

Ms. Neera Chatterjee  
Office of General Counsel  
The University of Texas System  
201 West Seventh Street  
Austin, Texas 78701-2902

OR2013-11123

Dear Ms. Chatterjee:

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# 491841 (OGC# 149540).

The University of Texas Southwestern Medical Center (the "university") received a request for all documents maintained by the university regarding a specified clinical trial to include the trial protocol, previous study results, and any related promotional literature used by the university.<sup>1</sup> You claim the submitted information is excepted from disclosure under section 552.101 of the Government Code. You further state release of the submitted information may implicate the proprietary interests of NeoSync, Inc. ("NeoSync"). Accordingly the university notified NeoSync of the request for information and of its rights to submit arguments to this office as to why the information should or should not be released. *See Gov't Code § 552.305(d)*; Open Records Decision No. 542 (1990) (statutory predecessor to section 552.305 permitted governmental body to rely on interested third party to raise and explain applicability of exception to disclosure under certain circumstances). We have received comments from NeoSync. We have considered the submitted arguments and reviewed the submitted representative sample of information.<sup>2</sup>

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<sup>1</sup>You inform us the university sought and received clarification of some of the information requested. *See Gov't Code § 552.222* (if request for information is unclear, governmental body may ask requestor to clarify request).

<sup>2</sup>We assume the "representative sample" of records submitted to this office are 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 those records contain substantially different types of information than those submitted to this office.

Section 552.101 of the Government Code excepts from public disclosure “information considered to be confidential by law, either constitutional, statutory, or by judicial decision.” Gov’t Code § 552.101. Section 552.101 encompasses information made confidential by other statutes, such as section 161.032 of the Health and Safety Code, which provides in relevant 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 and Subchapter A, Chapter 160, Occupations Code, do not apply to records made or maintained in the regular course of business by a hospital, health maintenance organization, medical organization, university medical center or health science center, hospital district, hospital authority, or extended care facility.

Health & Safety Code § 161.032(a), (c), (f) (footnote omitted). Section 161.031(a) defines a “medical committee” as “any committee . . . of . . . (3) a university medical school or health science center[.]” *Id.* § 161.031(a)(3). Section 161.0315 provides in relevant part “[t]he governing body of a hospital [or] 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[.]” *Id.* § 161.0315(a).

The precise scope of the “medical committee” provision has been the subject of a number of judicial decisions. *See, e.g., Memorial Hosp.—The Woodlands v. McCown*, 927 S.W.2d 1 (Tex. 1996); *Barnes v. Whittington*, 751 S.W.2d 493 (Tex. 1988); *Jordan v. Fourth Supreme Judicial Dist.*, 701 S.W.2d 644 (Tex. 1986). These cases establish “documents generated by the committee in order to conduct open and thorough review” are confidential. This protection extends “to documents that have been prepared by or at the direction of the committee for committee purposes.” *Jordan*, 701 S.W.2d at 647-48. Protection does not extend to documents “gratuitously submitted to a committee” or “created without committee impetus and purpose.” *Id.* at 648; *see also* Open Records Decision No. 591 (1991) (construing, among other statutes, statutory predecessor to section 161.032).

You state the Institutional Review Board (the “IRB”) is a medical committee established pursuant to federal law in order to review and approve research involving human subjects at the university and other affiliated hospitals. *See* 21 C.F.R. § 56.102(g). Based on your

representations, we agree the IRB constitutes a medical committee as defined by section 161.031. You state the submitted information was "prepared for or by the IRB" for the purpose of assessing the research involving human subjects that would be performed by university employees. Based on your representations and our review, we agree the submitted information consists of records of the IRB prepared by or at the direction of the IRB for committee purposes. Accordingly, the university must withhold the submitted information under section 552.101 of the Government Code in conjunction with section 161.032 of the Health and Safety Code. As our ruling is dispositive, we need not address the remaining arguments against the disclosure of the submitted information.

This letter ruling is limited to the particular information 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 information or any other circumstances.

This ruling triggers important deadlines regarding the rights and responsibilities of the governmental body and of the requestor. For more information concerning those rights and responsibilities, please visit our website at [http://www.oag.state.tx.us/open/index\\_orl.php](http://www.oag.state.tx.us/open/index_orl.php), or call the Office of the Attorney General's Open Government Hotline, toll free, at (877) 673-6839. Questions concerning the allowable charges for providing public information under the Act must be directed to the Cost Rules Administrator of the Office of the Attorney General, toll free, at (888) 672-6787.

Sincerely,



Ana Carolina Vieira  
Assistant Attorney General  
Open Records Division

ACV/ag

Ref: ID# 491841

Enc. Submitted documents

c: Requestor  
(w/o enclosures)

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Boston, Massachusetts 02110  
(w/o enclosures)