

**IN THE UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT COURT  
SOUTHERN DIVISION**

<b>BILLY RYAN LOONEY, ET AL.,</b>	)	
	)	
<b>Plaintiffs,</b>	)	
	)	
<b>v.</b>	)	<b>CIVIL ACTION NO.</b>
	)	<b>2:13-CV-00733-KOB</b>
<b>SHEILA D MOORE, ET AL.,</b>	)	
	)	
<b>Defendants.</b>	)	

**MEMORANDUM OPINION**

This case involves a clinical research trial performed on premature infants with low birth weights. The purported class action suit brought by the infant Plaintiffs, by and through their parents, alleges that the members of the University of Alabama at Birmingham Institutional Review Board were negligent and lacked the informed consent of the participants, among other allegations. (Doc. 32).

This matter comes before the court on “Plaintiffs’ Motion to Compel Production of Institutional Review Board Documents Allegedly Protected by the Peer-Review Privilege.” (Doc. 45). In their motion, Plaintiffs ask the court to compel UAB to produce the documents generated by the Institutional Review Board (“IRB”) relating to “Surfactant Positive Pressure, and Oxygenation Randomized Trial” (“SUPPORT”). Defendants argue that the IRB’s documents are privileged under Alabama Code § 22-21-8. (Doc. 46). The substance of both parties’ arguments focuses on whether § 22-21-8 applies to the UAB IRB.

For the reasons discussed below, the court finds that the privilege from § 22-21-8 applies

to the UAB IRB. Therefore, the court will deny the motion to compel without prejudice to Plaintiffs refiling at a later time, if necessary.

**I. Alabama Code § 22-21-8 Applies to the UAB IRB**

The key point of contention among the parties is whether Alabama Code § 22-21-8 applies to the UAB IRB documents and, even if it applies, whether federal regulations preempt its use here. The application of this particular statute to an IRB is a matter of first impression in Alabama, although other state and federal courts have addressed the peer review privilege statutes of other states that have varying degrees of similarity to the Alabama version.

The function of § 22-21-8 is to render certain materials confidential and prevent those materials from being “subject to discovery or introduction in evidence in any civil action against a health care professional or institution arising out of matters which are the subject of evaluation and review for accreditation, quality assurance or similar functions, purposes, or activities.” Ala. Code § 22-21-8 (1975). On its face, § 22-21-8 applies to “materials prepared by an employee, advisor, or consultant of a hospital, clinic, or medical staff and to materials prepared by an employee, advisor or consultant of an accrediting, **quality assurance or similar agency** or similar body . . . .” *Id.* (emphasis added).

The Alabama Supreme Court has noted the title of the Act creating the statute—“To provide for the confidentiality of all written materials and activities concerning the accreditation, quality assurance, or similar function of any hospital, clinic, or medical staff”—and interpreted § 22-21-8 expansively, “[g]iven the broad language used by the Legislature in the title of the Act.” *Ex parte Krothapalli*, 762 So. 2d 836, 838-39 (Ala. 2000) (holding that physician’s applications for staff privileges were protected by § 22-21-8, but that the statute would not

preclude discovery of records obtained from sources other than the hospital review committee).

As such, the primary questions for this court are whether (1) the IRB's documents were created for quality assurance purposes, (2) the IRB's documents are needed to guarantee the high quality of care for patients, and (3) the confidentiality of the reports and statements is necessary. *See Ex parte Fairfield Nursing & Rehab. Ctr., L.L.C.*, 22 So. 3d 445, 450 (Ala. 2009). In support of its position that the privilege applies, UAB submitted affidavits describing the purpose, function, and practices of the UAB IRB. (Docs. 46-1, 46-2). The affidavits for Sheila Moore and Dr. Ferdinand Urthaler provide compelling evidence that the IRB's function regarding SUPPORT involved evaluating and seeking to improve the quality of health care, as well as evaluating the qualifications, competence, and performance of providers of health care. The affidavits also address the necessity of confidentiality to the integrity of the IRB process. Thus, the IRB documents appear to fall in the protection of § 22-21-8.

Plaintiffs rely on three cases finding that IRBs are not entitled to protection under state peer review statutes. In two of these cases, however, the underlying statute at issue, unlike the Alabama statute, made no mention of quality assurance. *See P.J. v. Utah*, 247 F.R.D. 664 (D. Utah 2007) (examining Utah Code Ann. § 26-25-3); *Esdale v. Am. Cmty. Mut. Ins. Co.*, No. 94C4600, 1995 WL 263479, at \*2 (N.D. Ill. May 3, 1995) (examining Texas Health and Safety Code, § 161.032 and § 5.06 of Texas Revised Civil Statutes Annotated 4495b). Furthermore, in all three of these cases that Plaintiffs cite, the courts narrowly construed the underlying peer review privileges. *See Konrady v. Oesterling*, 149 F.R.D. 592 (D. Minn. 1993) (turning on the fact that the Minnesota Supreme Court considered the privilege to be "narrowly limited"); *P.J.*, 247 F.R.D. at 671 (noting that caution should be used in expanding the role of the federal

common law of privilege in discovery); *Esdale*, 1995 WL 263479, at \*3 (noting that “because evidentiary privileges operate to exclude relevant evidence and therefore to block the judicial fact finding function, they are not favored and, where recognized must be narrowly construed.”). In *Esdale*, the one case where the federal court itself imposed the narrow construction rather than relying on a narrow construction from the state court, the Office of the Attorney General of Texas subsequently issued an opinion disagreeing with the Northern District of Illinois’s interpretation of Texas law in *Esdale*. Tex. Atty. Gen. Op. OR2001-0912 (Tex. A.G.) (“[I]n contrast to the *Esdale* court, this office does believe the Texas legislature intended to cover entities such as the IRB . . .”).

Here, however, Alabama courts have broadly interpreted § 22-21-8. *See Krothapalli*, 762 So. 2d at 838-39. Thus, this case becomes more analogous to those cases finding IRBs to be protected under the peer review privilege. *See KD*, 715 F. Supp. 2d at 593 (quoting *Baltimore Sun Co. v. Univ. of Md. Sys. Corp.*, 584 A.2d 683, 687 (1991)) (finding the peer review privilege applied to the IRB, in part, because Maryland’s statute “provided ‘broad statutory protection’”); *Pomona Valley Hosp. Med. Ctr. v. Supreme Ct. of Los Angeles Cnty.*, 209 Cal. App. 4th 687, 686 (Cal. Ct. App. 2012) (holding that “California’s protection is broader than Minnesota’s peer review statute.”); *Doe v. Ill. Masonic Med. Ctr.*, 696 N.E. 2d 707, 710 (Ill. App. Ct. 1998) (holding that “the Illinois statute is broader than the Minnesota statute construed in *Konrady*”). Given the broad scope of the Alabama privilege supported by the language of the statute, the court finds that the documents generated by the IRB are privileged under § 22-21-8 because they involve quality assurance review of the SUPPORT program.

## **II. Federal Law Does Not Preempt Alabama Code § 22-21-8**

Plaintiffs argue that the federal statutes and regulations governing Institutional Review Boards—42 U.S.C. § 289 and 45 C.F.R. §§ 46.101 *et seq.*—preempt the application of Alabama Code § 22-21-8. Whether these federal statutes and regulations preempt any state peer review privileges is an issue of first impression in the Eleventh Circuit. The court finds that nothing in these statutes or regulations evidences a Congressional intent to preempt state peer review privileges. The federal statutes and regulations in question make no mention of civil discovery much less peer review privileges, and “congressional and regulatory silence usually defeats a claim of preemption, not the other way around.” *Planned Parenthood of Ind., Inc. v. Comm’r of Indiana State Dept. Health*, 699 F.3d 962, 985 (7th Cir. 2012) (citing *Wyeth v. Levine*, 555 U.S. 555 (2009) (Thomas, J., concurring in the judgment)).

Moreover, the fact that a division of HHS, the agency promulgating the regulations in question, argued under similar circumstances that Maryland’s peer review privilege protected its IRB strongly suggests that the IRB regulations were not intended to preempt Alabama’s peer review privilege. *See KD v. U.S.*, 715 F. Supp. 2d 587, 588 (D. Del. 2010) (finding the National Heart Blood and Lung Institute’s IRB documents were protected under Maryland’s peer review privilege). As a result, the court finds that 45 C.F.R. §§ 46.101 *et seq.* do not preempt Alabama Code § 22-21-8.

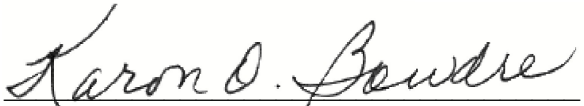
## **III. Conclusion**

For these reasons, the court finds that the § 22-21-8 privilege applies to the UAB IRB. However, the parties have argued in generalities about certain documents at issue without identifying the precise documents sought by Plaintiffs or withheld by Defendants. In fact, the

Defendants admit that the privilege does not apply to some documents within the IRB records that can be obtained from other sources but without precise description. In short, the court has insufficient information concerning what documents have been produced and which withheld documents Plaintiffs still seek to determine whether specific documents are within or without the protection of the privilege. This imprecision prevents the court from carefully crafting limitations to guide the parties in discovery.

The court ORDERS the parties to communicate in an attempt to agree among themselves on which documents should be covered by the privilege based on this court's finding that the privilege generally applies to the UAB IRB. The court DENIES the motion to compel WITHOUT PREJUDICE to Plaintiffs' refiling at a later time if the parties are unable to agree on the scope of the privilege as to particular documents.

DONE and ORDERED this 12th day of May, 2014.

  
KARON OWEN BOWDRE  
CHIEF UNITED STATES DISTRICT JUDGE