A recent case in Alabama highlights the importance of filling out informed consent papers thoroughly in order to avoid ending up in a courtroom.

**Source**: Physicians Practice

Informed consent is a law that often lands physicians in court. A recent case serves as a reminder of its importance.

When a patient thinks of informed consent, they usually relate it to signing a form to give permission for treatment or a procedure (e.g., surgery) or to participate in a clinical trial. From a bioethical standpoint, the objective is to make sure the patient not only understands what they are consenting to and the possible adverse outcomes but, also, relays that understanding back to the provider.

Federal regulations governing informed consent are known as the Common Rule and are found at 45 C.F.R. Part 46 (Subpart A). According to the Presidential Commission for the Study of Bioethical Issues, "In research, the informed consent process primarily serves two purposes - to educate individuals about the risks and potential benefits of their possible participation in research, and to establish the voluntary willingness of the individual(s) to participate. The informed consent process, which is outlined by investigators and must be approved by an institutional review board (IRB), can differ depending on the research project."

Recently, the 11th Circuit Court of Appeals certified a question to the Alabama Supreme Court after it identified two issues: (1) whether under Alabama law a free-standing tort exists for lack of informed consent even if there was no injury from the procedure and; (2) if an injury was required for an informed consent claim, did the same rule also apply in the context of a clinical study. In Lewis v. Moore, No. 15-13979 (11th Cir. July 6, 2017), the appellate court considered a case arising from a clinical study at the University of Alabama at Birmingham, which conducted a study on premature infants and oxygen saturation.

The threshold issue focused on whether the injuries were derived from the study or from the premature birth. In essence, in tort law, it is a causation issue. The takeaways for physicians from this case include the following:

• Make sure that the informed consent form is comprehensive and detailed;
• Gain understanding from the patient or their representative; and
• Review forms to make sure that the regulatory and state requirements are met.


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