

# Strict Liability for Lack of Informed Consent in Clinical Trials

## CLIENT ALERT

### WRITTEN BY

Ronni E. Fuchs | Scott G. Robinson

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Forty-five years ago, a scandalous medical experiment in Alabama caused the United States to reexamine the concept of informed consent. While that scrutiny continues today, a recent case from Alabama, *Looney v. Moore*, rejected an invitation to provide clinical trial patients recovery for failure of informed consent in the absence of provable injury.

In 1972, the Associated Press broke the story of the Tuskegee Syphilis Study, a federally funded experiment on unsuspecting African-Americans with syphilis in rural Alabama. In the study, medical researchers and health providers withheld treatment from hundreds of men from 1932 to 1972 in order to study the course of the untreated disease. Researchers did not obtain informed consent from the men, who “were persuaded to participate by promises of free transportation to and from hospitals, free hot lunches, free medical treatment for ailments other than syphilis and free burial.” Even after penicillin became the standard for treating syphilis in 1945, researchers did not offer it to the study participants.<sup>1</sup>

In the wake of the disclosure of the Tuskegee Syphilis Study, Congress created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission’s report, the Belmont Report, set forth ethical principles to govern future human research, including the requirement of adequate standards for informed consent that recognize prospective research subjects must “be given the opportunity to choose what shall or shall not happen to them.”<sup>2</sup>

In addition to a class action lawsuit, a settlement and a presidential apology, the Tuskegee Study gave rise to the current model for informed consent in the United States.<sup>3</sup> The informed consent process involves three key features: (1) disclosure of the information needed to make an informed decision; (2) understanding by the research subject of what has been disclosed; and (3) a voluntary decision about whether or not to participate in the research.<sup>4</sup> Informed consent must be legally effective and prospectively obtained.

### History of Clinical Trial Informed Consent Cases

Based on these core concepts of modern informed consent, there have been lawsuits challenging the adequacy of informed consent in clinical studies. In addition to allegations of failure to disclose potential risks from the research (or the likelihood of such risks occurring), some of these cases also allege that researchers failed to inform subjects of the researchers’ financial interest in the new therapy. Other cases have included unique allegations, including falsification of Institutional Review Board approval or the failure to inform the patient that the delay in

active treatment due to being randomized into the placebo arm might risk permanent harm.<sup>5</sup>

Many clinical trial informed consent cases settled quickly. One of the only cases to go to trial was a case brought against the bone marrow transplant center at Fred Hutchinson following the deaths of five research participants. In that case, a jury returned a defense verdict after finding that the plaintiffs did not prove that any missing information would have changed the patients' decisions to participate in the research.<sup>6</sup>

The plaintiffs in all these cases shared one thing: They were all injured. A recent case arising in Alabama proposed to hold researchers liable for failure of informed consent in a clinical trial *in the absence of physical injury*.

### **Looney Case**

The clinical trial at issue was performed at the University of Alabama. Premature infants were treated with varying levels of oxygen — all within the standard of care — in order to determine the ideal oxygen percentage. Following an investigation, the U.S. Office of Human Research Protection found the informed consent to be inadequate due to a failure to describe how the risks of blindness, neurological damage and death were affected by the varying levels of oxygen exposure, and how those risks differed from the risks incurred by premature infants not participating in the study. The infants' parents sued, alleging that their children's participation was based on a lack of informed consent and that the participation caused their injuries. The plaintiffs brought claims for negligence, negligence per se, breach of duty and products liability, in addition to lack of informed consent. The U.S. District Court for the Northern District of Alabama dismissed all of the plaintiffs' claims because their own experts were unable to conclude that participation in the study, rather than premature birth and low birthweight, caused the injuries.

The Eleventh Circuit affirmed the district court's dismissal of all claims, except lack of informed consent. The court found that it was not clear under Alabama law whether a plaintiff must "prove that an injury actually resulted from the medical treatment in order to succeed on a claim that his consent to the procedure was not informed."<sup>7</sup> The Eleventh Circuit certified the question to the Alabama Supreme Court, which declined to resolve the issue, without comment.

Had the Alabama Supreme Court recognized a cause of action for failure to provide informed consent in the absence of injury, it would have created a strict liability cause of action on the basis of dignity harm alone. Such an expansion of liability would be contrary to the overwhelming case law that requires actual injury for relief.<sup>8</sup> The few courts that have addressed the issue of informed consent in the context of clinical trial injuries have treated the claim as one sounding in negligence, which requires causation and actual injury.<sup>9</sup>

In fact, only one state — Pennsylvania — may treat claims for lack of informed consent otherwise; Pennsylvania courts have suggested that they would treat them as battery claims, which do not require injury.<sup>10</sup> All other states distinguish between claims of "lack of consent" and "lack of *informed* consent," with the former falling into the category of battery, and the latter falling into the category of negligence.

Recognizing that state laws almost universally view lack of informed consent claims as negligence-based claims that require actual injury, on March 30, the Eleventh Circuit held that Alabama law requires the same. In reaching this decision, the court pointed first to indications from Alabama case law that the "injury" requirement of the

Alabama Medical Liability Act (AMLA) applies to informed consent claims, just as it does to traditional medical malpractice claims based on negligent treatment.<sup>11</sup> As the Eleventh Circuit stated, “it seems a bit incongruous that a patient subjected to negligent medical treatment is required to show that the treatment caused his injury, while a person whose only beef is that he was not fully informed of the risks of a procedure could prevail even if he suffered no injury at all.”<sup>12</sup>

Even if the AMLA did not apply to the plaintiffs’ claims, the Eleventh Circuit held, Alabama common law governing negligence actions also requires an injury.<sup>13</sup> The plaintiffs’ attempts to take their claims out of the negligence realm by analogizing informed consent claims to intentional battery were unavailing. The Eleventh Circuit found that Alabama, like most other states, distinguishes between a “lack of consent” claim sounding in battery and a “lack of informed consent” claim sounding in negligence.<sup>14</sup> Because the plaintiffs acknowledged that they consented to the specific conduct at issue, and alleged only that their consent was not fully informed, the Eleventh Circuit found that a battery framework was not appropriate.<sup>15</sup>

While plaintiffs in clinical trial informed consent cases may continue to propose novel strict liability causes of action on the basis of dignity harm alone, *Looney* holds that informed consent claims under Alabama law — like those under the law of almost every state in which the issue has been addressed — sound in negligence and thus require an actual injury.

## Endnotes

<sup>1</sup> Jean Heller, “AP WAS THERE: Black men untreated in Tuskegee Syphilis Study,” AP News May 2017, reprinting July 25, 1972 AP story, *available* at <https://apnews.com/e9dd07eaa4e74052878a68132cd3803a/AP-WAS-THERE:-Black-men-untreated-in-Tuskegee-Syphilis-Study> (accessed Sept. 13, 2017).

<sup>2</sup> U.S. Department of Health & Human Services, Office of Human Research Protections, Informed Consent Frequently Asked Questions, <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html> (accessed Sept. 13, 2017).

<sup>3</sup> Centers for Disease Control & Prevention, The Tuskegee Timeline, <https://www.cdc.gov/tuskegee/timeline.htm> (accessed Aug. 2, 2017).

<sup>4</sup> *Id.* HHS regulations at 45 CFR 46.116 and 45 CFR 46.117 describe the informed consent requirements for federally funded clinical trials, while FDA regulations at 21 CFR part 50 govern those for trials done pursuant to FDA approval.

<sup>5</sup> See, e.g., *Hamlet v. Genentech*, No. 03-CVS-1161 (N.C. Sup. Ct. 2003).

<sup>6</sup> “When Clinical Trials Fail,” ABA Journal, June 1, 2004, [http://www.abajournal.com/magazine/article/when\\_clinical\\_trials\\_fail](http://www.abajournal.com/magazine/article/when_clinical_trials_fail) (accessed August 2, 2017).

<sup>7</sup> *Looney v. Moore*, No. 15-13979 (11th Cir. 2017).

<sup>8</sup> See, e.g., *Canterbury v. Spence*, 464 F.2d 772, 790 (D.C. Cir. 1972) (“An unrevealed risk that should have been made known must materialize, for otherwise the omission, however unpardonable, is legally without consequence.”); *Downer v. Veilleux*, 322 A.2d 82, 92 (Me. 1974) (“As in the case of any breach of a legal duty, the plaintiff must, as in malpractice actions generally, prove a proximate causal relationship between the physician’s failure to adequately inform and injury to the patient.”). See also Roger B. Dworkin, *Medical Law and Ethics in the Post-Autonomy Age*, 68 Ind. L.J. 727, 729 (1993) (stating that “the loss of dignity, autonomy, free choice, and bodily integrity that is so exalted in the rhetoric of informed consent is worth nothing at judgment time”).

<sup>9</sup> See, e.g., *Stewart v. Cleveland Clinic Found.*, 736 N.E.2d 491, 501 (Ohio Ct. App. 1999) (“the unrevealed risks and dangers which should have been disclosed by the physician actually materialize and are the proximate cause of the injury to the patient”); *Lenahan v. Univ. of Chicago*, 808 N.E.2d 1078, 1082-83 (Ill. Ct. App. 2004) (describing an informed consent claim as a negligence claim, and requiring “an injury proximately caused by the breach”); *Compton v. Pass*, No. 260362, 2010 Mich. App. LEXIS 556 (Mich. Ct. App. Mar. 23, 2010) (stating that a claim under the “doctrine of informed consent” involves the same elements as a medical malpractice claim, including “an injury” and that “the breach proximately caused the injury”).

<sup>10</sup> See, e.g., *Montgomery v. Bazaz-Sehgal*, 798 A.2d 742, 748-49 (Pa. 2002) (stating that a claim for “informed consent sounds in battery”); *Rowinsky v. Sperling*, 452 Pa. Super. 215, 224-25 (Pa. Super. Ct. 1996) (holding that where plaintiff established that she was not informed of certain risks, recovery was “permitted under the doctrine of informed consent, regardless of causation and actual damages”). But see *Cochran v. Wyeth*, 3 A.3d 673 (Pa. Super. Ct. 2010) (treating a claim for lack of informed consent as analogous to negligent failure to warn, and holding that a plaintiff cannot prove proximate causation when the nondisclosed risk did not materialize in injury — “In informed consent cases it appears to be well-settled and without debate that the non-disclosed risk must manifest itself into actual injury in order for a plaintiff to establish proximate causation.”).

<sup>11</sup> *Looney v. Moore*, No. 15-13979, 2018 U.S. App. LEXIS 8070 at \*16 (11th Cir. Mar. 30, 2018) (citing *Houston Cnty. Health Care Auth. v. Williams*, 961 So. 2d 795, 810 (Ala. 2006) (stating as a general matter that all of the claims in the case, including claims for lack of informed consent, were governed by the AMLA because they “allege a medical injury arising in the context of their patient-hospital relationship as the basis for each of their claims”)).

<sup>12</sup> *Id.* at \*17. The court acknowledged contrary Alabama cases that neglected to mention the AMLA “injury” requirement when describing the elements of an informed consent claim, but concluded that because each of those cases involved a clear, serious injury, reference to the requirement was unnecessary. *Id.* (citing *Giles v. Brookwood Health Services, Inc.*, 5 So. 3d 533, 533-34 (Ala. 2008); *Phelps v. Dempsey*, 656 So. 2d 377, 377 (Ala. 1995)).

<sup>13</sup> See *id.* at \*23.

<sup>14</sup> *Id.* at \*21-22 (citing *Cain v. Howorth*, 877 So. 2d 566 (Ala. 2003) (“The law distinguishes between a total lack of consent for the contested act (battery) and the lack of informed consent (negligence).”).

<sup>15</sup> See *id.* at \*22.

*Ronni Fuchs is a partner in Pepper Hamilton's [Health Sciences Department](#), a team of 110 attorneys who collaborate across disciplines to solve complex legal challenges confronting clients throughout the health sciences spectrum. Scott Robinson is an associate in the Health Sciences Department.*

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