V. THE CASE LAW

The great bulk of what is called *law* takes the form of the published case law, also called *opinions*. Opinions are written by the judge presiding over the case. The published case law results from courtroom cases held before a judge, or a panel of judges. It is rare that a judge will create a law that is entirely new. What almost always occurs is that the judge incorporates elements from the existing case law into his or her own published opinion. This practice is called *stare decisis*, pronounced "stah-ray dee-SIGH-siss."

Published courtroom opinions cover various issues relevant to consent forms. One interesting issue is whether a subject needs to be informed of a potentially toxic side effect that represents only a small risk (under 1% risk). This particular issue can be found in a variety of opinions, notably, *Scott v. Wilson* (25) *Cobbs v. Grant* (26) *Canterbury v. Spence* (27,28) *Truman v. Thomas* (29) *Cruzan v. Director* (30) *Halushka v. University of Saskatchewan* (31,32) and *Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees* (33).

Investigators, medical writers, and attorneys can easily find additional guidance by reading subsequent case law that cites these opinions. The best source of guidance for drafting consent forms is a seasoned attorney, familiar with the case law, and having experience in drafting consent forms.

VI. BASIS FOR CONSENT FORMS IN THE CODE OF FEDERAL REGULATIONS

Rules relating to consent forms are found in Title 21, which applies to the FDA. Rules relating to consent forms also appear in Title 45, which applies to the Department of Health and Human Services (DHHS). The FDA and DHHS are different agencies in the U.S. government. But the two sets of rules are quite similar to each other.

The following concerns Title 45 of the CFR. The DHHS oversees the registration of Institutional Review Boards (IRB). An IRB is a small group of volunteers, independent from any given clinical study, consisting of medical experts and laypersons. The IRB reviews and approves consent forms for any given clinical study. Title 45, Part 46, Sections 107–117, provide a legal basis for the IRB and for consent forms.

[25] Scott v. Wilson. 396 S.W.2d 532; 1965 Tex. App. LEXIS 2153.
[26] Cobbs v. Grant. 8 Cal. 3d 229; 502 P.2d 1; 104 Cal. Rptr. 505; 1972 Cal. LEXIS 278.
[27] Canterbury v. Spence. 464 F.2d 772; 150 U.S. App. D.C. 263; 1972 U.S. App. LEXIS 9467.
[28] Couture JJ. The changes in informed consent in experimental procedures: the evolution of a concept. *J Health & Biomed L*. 2004;1:125–161.
[29] Truman v. Thomas. 27 Cal. 3d 285; 611 P.2d 902; 165 Cal. Rptr. 308; 1980 Cal. LEXIS 175.
[30] Cruzan v. Director, Missouri DMH, 497 U.S 261, 110 S.Ct. 2841 (1990).
[31] Halushka v. University of Saskatchewan et al. (1965), 53 D.L.R. (2d) 436 (Sask. C.A.).
[32] Tremayne-Lloyd T, Srebrolow G. Research ethics approval for human and animal experimentation: consequences of failing to obtain approval – including legal and professional liability. *J Can Chiropract Assoc*. 2007;51:56–60.
[33] Salgo v. Leland Stanford Jr. University Board of Trustees. 154 Cal. App. 2d 560; 317 P.2d 170; 1957 Cal. App. LEXIS 1667.