

- (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.
- (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
- (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
- (8) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Many academic medical centers voluntarily comply with the federal rules, regardless of the source of funding. Only five states in the United States of America, which has 50 states in all, have state laws requiring application of the federal rules to all research conducted with human subjects regardless of the source of funding (34).

VII. SUMMARY

Consent forms used in clinical trials need to conform with the administrative law set forth in the CFR. The conditions imposed by the consent form of the *Yellow Fever Commission* have parallels with the conditions set forth in the CFR. What was, and is, required is that the study subject understands that the clinical study is an experiment (and is not a treatment), that risks be explained to the study subject, that medical treatment will be available if the clinical study results in injury to the study subject, and that participation in the clinical trial is voluntary.

VIII. EXAMPLES OF CONTEMPORARY CONSENT FORMS

The following provides, in its entirety, a consent form used for a study of lung cancer (35,36,37). The consent form uses a standard format. In reviewing this particular consent form, the reader might want to keep an eye on [Table 29.1](#). This table contains terms familiar to the layperson (should be in consent forms) and the corresponding medical terms (should be avoided in consent forms) (38).

³⁴ Shamoo AE, Katzel LI. How should adverse events be reported in US clinical trials?: ethical considerations. *Clin Pharmacol Ther.* 2008;84:275–278.

³⁵ Cella D. Consent form was developed by Peter Raich for an ECOG study. E-mail of November 9, 2009.

³⁶ Coyne CA, Xu R, Raich P, et al. Randomized, controlled trial of an easy-to-read informed consent statement for clinical trial participation: a study of the Eastern Cooperative Oncology Group. *J Clin Oncol.* 2003;21:836–842.

³⁷ Permission to reproduce provided by Dr. P.C. Raich. E-mail of April 6, 2011.

³⁸ Coyne CA, Xu R, Raich P, et al. Randomized, controlled trial of an easy-to-read informed consent statement for clinical trial participation: a study of the Eastern Cooperative Oncology Group. *J Clin Oncol.* 2003;21:836–842.