

be aware of 21 CFR 50, which is entitled Informed Consent Elements, which was published in the Federal Register in January 2011 (17).

III. GUIDANCE FOR INDUSTRY

For regulated clinical trials, the FDA provides guidance in the form of a collection of about 50 short essays, called Guidance for Industry. These Guidance for Industry documents are clearly written, but they are not detailed, they are rarely revised, and they cover only selected topics relating to FDA-sponsored trials. The Guidance for Industry documents do not have the force of the law.

Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance (18) concerns consent forms. Informed consent is defined as:

A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form.

This Guidance for Industry E6 (19) states that the consent form, and relevant instructions to the study subject should include explanations that:

- (a) That the trial involves research.
- (b) The purpose of the trial.
- (c) The trial treatment and the probability for random assignment to each treatment.
- (d) The trial procedures to be followed, including all invasive procedures.
- (e) The subject's responsibilities.
- (f) Those aspects of the trial that are experimental.
- (g) The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant.
- (h) The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.
- (i) The alternative procedure or course of treatment that may be available to the subject, and their important potential benefits and risks.
- (j) The compensation and/or treatment available to the subject in the event of trial-related injury.
- (k) The anticipated pro-rated payment, if any, to the subject for participating in the trial.
- (l) The anticipated expenses, if any, to the subject for participating in the trial.
- (m) That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled.

¹⁷ Federal Register. January 4, 2011;76(2):256.

¹⁸ U.S. Department of Health and Human Services. Food and Drug Administration. Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance. April 1996.

¹⁹ U.S. Department of Health and Human Services. Food and Drug Administration. Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance. April 1996.