

The plaintiff's attorney asks the plaintiff, "Did you know what you needed to know in order to agree to participate?" or "Had you known x, would you have agreed?"

Lesson: A subject needs to know what it is important for that subject to know for that person to make a decision at that time. The following are the minimum requirements.

## **A. THE EIGHT REQUIRED ELEMENTS OF CONSENT (FDA 21 CFR 50.25) (DHHS 45 CFR 46.116a)**

1. A statement that the study involves research, an explanation of the purposes of the research, *(NOTE: the purpose is to answer a question; it is not to "treat" a patient.)* and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
2. A description of any reasonably foreseeable risks or discomforts to the subject.
3. A description of any benefits to the subject or to others which may reasonably be expected from the research.
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained  
(FDA: and that notes the possibility that the Food and Drug Administration may inspect the records.  
(ICH, a statement that other similar regulatory agencies from other countries may audit the records).
6. For research involving more than minimal risk, *(NOTE: not all studies do!)*  
an explanation as to whether any compensation and  
an explanation as to whether any medical treatment 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 subject's 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.

## **B. CALIFORNIA'S ADDITIONAL REQUIRED ELEMENTS**

These are California elements that are not represented among the FDA's required elements.

1. If a placebo is to be administered or dispensed to a portion of the subjects involved in a medical experiment, all subjects of such experiment shall be informed of that fact.
2. An estimate of the expected recovery time of the subject after the experiment.
3. The name, institutional affiliation, if any, and address of the person or persons actually performing and primarily responsible for the conduct of the experiment,
4. The name of the sponsor or funding source, if any, or manufacturer if the experiment involves a drug or device, and the organization, if any, under whose general aegis the experiment is being conducted.
5. The name, address, and phone number of an impartial third party, not associated with the experiment, to whom the subject may address complaints about the experiment.
6. Subjects must be given a copy of the Experimental Subject's Bill of Rights.

## **C. THE ADDITIONAL OPTIONAL ELEMENTS OF CONSENT**

When these elements are applicable, they are not optional but are required.

When these elements are not applicable, they are optional and are not required.

As they may add length without meaning, carefully consider whether the information is applicable to the study and proposed subject population.

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
3. Any additional costs to the subject that may result from participation in the research.
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
6. The approximate number of subjects involved in the study.

