

## EXPERIMENTATION WITH HUMAN SUBJECTS CALIFORNIA LAW AND REGULATION

On July 7, 1978 Governor Jerry Brown signed into law the Protection of Human Subjects in Medical Experimentation Act. The Act was amended in 2001 to clarify the hierarchy of those who can be a Legally Authorized Representative under the Common Rule. The Act provided for informed consent and for an Experimental Subjects Bill of Rights.

### “MEDICAL EXPERIMENT” Section 24174

The law applies to medical research and to clinical investigations and to “things done in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting the subject.”

- The risks are those “reasonably to be expected” instead of those that are “reasonably foreseeable.”
- Expected recovery time.

4. Consent is voluntary etc.

NOTE: An institution with an assurance may use the form approved with the Common Rule elements

### EXPERIMENTAL SUBJECTS BILL OF RIGHTS Section 24172

A printed list of the ten elements of consent that are also written out in the consent form. It is to be signed and dated by the person signing the consent form.

### WHO CAN GIVE INFORMED CONSENT Section 24175

1. The subject
2. A conservator under the Probate code
3. A designee under the Welfare and Institutions Code
4. A gravely disabled person with no conservator can have a designee under H&W code 4655(c)
5. Someone else but only for
  1. procedures intended to maintain or improve the subject’s health or
  2. obtaining information about a pathological condition of the subject.

### INFORMED CONSENT Section 24173

NOTE: An institution with an assurance may use the form approved with the Common Rule elements

Definition: the authorization given ... to have a medical experiment performed after (four) conditions have been satisfied

1. The Experimental Subjects Bill of Rights is provided and is signed and dated.
2. A written consent form is signed and dated by the correct person
3. Ten elements of consent are conveyed verbally and orally. Primary differences from 21 CFR 50.20 include:
  - The name and address of the sponsor or funding source

### PENALTIES Section 24176

Includes range financial penalties and possible prison time.

