

Informed Consent Form Check list (Human Research)

Requirements from California Health & Safety Code §24173 et. Seq and Title 45 CFR Part 46

The Informed Consent Form should provide the below items from number 1 through 19. Please make a special attention to the bolded numbers 1, 2a, 4, 14, 15, 18, & 19 when you check off this form.

<u>Informed Consent Element</u>	<u>Page-Line</u>
1. A copy of the California Experimental Subject's Bill of Rights included	-----
2. Language Requirements	
a. California law requires that the consent form and the Experimental Subject's Bill of Rights be written in a language in which the subject is fluent. In the beginning or at the end of the consent form, a statement such as <u>"I have read this information, which is printed in 'English, Spanish, Chinese, etc.'</u>. This is a language that I read and understand." should be stated.	-----
b. Understandable to lay person (avoid or explain technical terms)	-----
c. No exculpatory phrases	-----
d. Clearly written, no ambiguous phrases	-----
3. Fair Explanation of Procedures	
a. Purpose of experiment	-----
b. Identification of experimental aspects: For example, "My standard medication will be replaced by"	-----
c. Nature of drugs and dosages, route of administration	-----
d. Extent of experience with investigational drug	-----
4. DNA Testing (if applicable)	
a. Separate DNA informed consent form required	-----
b. Purpose of the DNA testing	-----
c. Clearly stated if DNA testing is mandatory or optional	-----
5. Name, affiliation & address, phone number, e-mail of person responsible for experiment	-----
6. Name of principal investigator (PI), funding source, manufacturer, authorizing organization	-----

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- 7. Investigator's offer to answer any questions -----

- 8. Name, address, phone number, & e-mail of impartial third party for addressing complaints:
the Panel requires the name, address, phone number, & e-mail of a qualified office or individual
that has been designated by the research institute or sponsor to have responsibility and authority
to follow up on complaints. -----

- 9. Risks to Subject
 - a. Discomforts -----
 - b. Drug side effects -----
 - c. Undiscovered drug toxicity -----
 - d. Long-term effects that cannot be known -----
 - e. Special risks in case of pregnancy (or possible pregnancy) -----

- 10. Possible Benefits
 - a. Therapeutic -----
 - b. Benefit (or none) to subject -----
 - c. To society (e.g., scientific knowledge) -----
 - d. To a PI of the research, the research institution or a manufacturer -----

- 11. Voluntary Participation
 - a. Clearly stated -----
 - b. Special risk populations -----
 - c. May withdraw from experiment without penalty -----

- 12. Disclosure of Financial Compensation
 - a. To investigator by study sponsor (if applicable) -----
 - b. To subject for participation in study (if applicable) -----

- 13. Alternative Procedures (drugs) for Therapy -----

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14. Policy regarding treatment and compensation provisions for injured research subjects, the Panel requires the following:

a. Should any complication derive from the procedures, the research subject will receive medical treatment. -----

b. If the sponsor/institute fails to offer to pay for the costs of the treatment, the consent form must state that a participant in the study always has the right of suit to recover compensation for damages directly caused by research procedures. -----

15. Confidentiality Statement

The Panel requires that a statement be included in the consent form advising potential research subjects that their records may be inspected by the Research Advisory Panel of California or State Regulatory Agencies -----

16. Signature by Subject -----

17. Signature by person administering consent to attest to adhering to informed consent procedures -----

18. Subject's Receiving a Copy Right

In the beginning or at the end, the informed consent form should include a statement such as "You will receive a copy of this signed informed consent form as well as a copy of the Experimental Subject's Bill of Rights." -----

19. Authorization to use and disclose protected health information (PHI) included -----