Informed Consent Form (ICF) Check List (Human Research)

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

The Informed Consent Form (ICF) should provide the below items from number 1 through 19.

IF 1, 2a, 3b, 14, 15, 18, & 19 ARE NOT INCLUDED IN THE ICF, THE RESEARCH ADVISORY PANEL WILL RETURN THE ICF AND POSTPONE THE APPLICATION ACCEPTING PROCESS UNTIL RECEIPT OF THE REVISED ICF WITH 1, 2b, 3b, 14, 15, 18, AND 19 ARE INCLUDED.

Informed Consent Elements — **Page #**

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 "I have read this information, which is printed in English, Spanish, Chinese, etc., 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. Explanation of Procedures

   a. Purpose of the study _____

   b. **Nature of study drug**: **Describe the Study Drug in Layman's terms including What the Study Drug is, What the study drug is for, and How the study drug works, Under the Purpose of the Study section, or In the First Part of the ICF** ----------

   c. Study drugs and dosages and route of administration ----------

4. **DNA Testing (if applicable)**

   Separate DNA informed consent form required ----------

   a. Purpose of the DNA testing included ----------

   b. Choice of DNA testing is mandatory or optional included ----------

5. Name, address, phone number, e-mail, and institutional affiliation, if any, of the Principal Investigator (PI). ----------

6. Name of the sponsor or funding source, manufacturer of a drug involved in the research, and the authorizing organization, if any ----------

Informed Consent Elements Cont. **Page #**

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 ----------

Informed Consent Elements Cont. **Page #**

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

a. If the sponsor/institute expressly offers to pay for the cost of the treatment for the injury, the consent form is not required to advise the subject of his/her right of suit to recover compensation for damages directly caused by research procedures. ----------

b. If the sponsor/institute fails to offer to pay for the costs of the treatment for the injury, this statement should be highlighted or bolded for the research subject to see clearly. ----------

AND 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 and PHI form advising potential research subjects that their records may be inspected by the Research Advisory Panel of California. ----------

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 ----------