



UC DAVIS OFFICE OF RESEARCH

AAHRPP Preparation UC Davis Human Research Part VI – The Elements of Consent

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Elements of Informed Consent

1. What are the expectations of an IRB member?
2. What are the regulatory required elements of informed consent?
3. What are the additional elements that could be applicable?
4. May the IRB waive or alter some of the elements of consent?

IRB Member Expectations

IRB Member Expectations

1. Determine whether the document includes all required elements. If an element is missing.
2. Consider whether any of the information listed in the optional elements should be included in the consent form.
3. Determine if any of the information is inaccurate, incomplete or not understandable.
4. Determine if any language in the consent form and try to determine if the language could unduly influence or coerce a potential subject into enrolling.
5. Notify the Committee Analyst of any issues you find so they can try to obtain a corrected document before the meeting.
6. If the consent document has not been revised and continues to be non-compliant at the time of the meeting, require the document to be revised before the PI can secure approval.



Required Elements

The 8 Mandatory Elements of Informed Consent

#1

Research Description

A statement that the study involves research, an explanation of the purposes of the research 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.

The 8 Mandatory Elements of Informed Consent

#2

Risks

A description of any reasonably foreseeable risks or discomforts to the subject.



The 8 Mandatory Elements of Informed Consent

#3

Benefits

A description of any benefits to the subject or to others which may reasonably be expected from the research



The 8 Mandatory Elements of Informed Consent

#4

Alternatives

A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.



The 8 Mandatory Elements of Informed Consent

#5

Confidentiality

A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.



The 8 Mandatory Elements of Informed Consent

#6

Compensation

For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.



The 8 Mandatory Elements of Informed Consent

#7

Contacts

An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights and whom to contact in the event of a research-related injury to the subject.



The 8 Mandatory Elements of Informed Consent

#8

Voluntary Participation and Withdrawal

A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.





Additional Elements

When Appropriate



Additional Elements, When Appropriate

#1

Unforeseeable Risks

A statement that the particular treatment or procedure may involve risks to the subject (or embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.



Additional Elements, When Appropriate

#2

Termination of Participation

Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

Additional Elements, When Appropriate

#3

Costs

Any additional costs to the subject that may result from participation in the research.



Additional Elements, When Appropriate

#4

Early Withdrawal

The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.



Additional Elements, When Appropriate

#5

New Findings

A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.



Additional Elements, When Appropriate

#6

Number of Subjects

The approximate number of subjects involved in the study.

$$N = \sum N(h)$$

May the IRB waive or alter some of the elements of consent?

Yes, an IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent ...

(source: 45 CFR 46.116(d))

Consent:
Description

Contacts
Voluntary participation
and withdrawal

Common Missed Elements

- Withdrawal of Subjects
 - What will happen with their data/biospecimen
- Future Specimen Banking
 - Protocol addresses banking, ICF does not
- Risk
 - Missing some or all of the outlined risk



Thank you – Don't miss Part VII of this continuing series!

