

INFORMED CONSENT

A. Basic Principles: In almost all cases, the researcher must obtain the informed consent of each subject to participate in the research. If the subject is not legally competent to give consent, consent must be obtained from the subject's legally authorized representative such as a parent, guardian, or conservator. The researcher should seek such consent only under circumstances that give the prospective subject or the representative sufficient opportunity to consider the matter carefully and that minimize the possibility of coercion or undue influence. The information that is given should be in language that is understandable to the subject or the representative. It should be a full, clear, but succinct explanation, without jargon or technical terms (in general, aimed to inform a person with at least 8 years of elementary school education).

No informed consent, whether oral or written, may include any language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, including release of the researcher, the sponsor, the University, or its agents from liability for negligence.

B. Elements of Informed Consent: In addition to the general requirements described above, federal regulations specify eight required elements of informed consent as well as six additional elements to be used when appropriate. The CPHS has incorporated federal and University guidance to provide the following outline of necessary elements for CPHS consent forms:

1. Heading and Title:

The consent form should be presented on UC Berkeley letterhead. It is helpful to include a heading such as "Consent to Participate in Research" as well as the study title at the top of the form. If the study has more than one subject group/consent form, designate appropriate sub-group after study title, e.g., "*Title of Study (Controls).*"

2. Introduction/Identification of Researchers:

The researcher's name, title/degree, and affiliation with the University should be stated. (The title of "Dr." should be used only for M.D.'s.)

3. Invitation to Participate:

State why the individual is being asked to take part in the study, using language that avoids any connotations of requirement or demand.

4. Purpose:

Explain the overall purpose of the study, including the fact that the study involves *research*. If appropriate, note the approximate number of subjects anticipated to take part in the study.

5. Procedures:

- Give a full description of the research procedures (including any *screening* procedures done for purposes of the study, unless there is a separate consent form for this).
- If a researcher is to deal directly with the human subject, describe what the subject will be expected to do, who will conduct the procedures, where and when they will take place, how often they will be performed, and how much time will be required for each procedure. Explain randomization and/or placebo if included in the study.
- Also state the *total time* expected for study participation.
- Identify any study procedures that are *experimental*. Make a clear distinction between those procedures that are in the interests of research and those that are part of standard treatment.
- Prospective respondents to surveys or interviews should be warned of any personal and/or sensitive questions. Describe any photographing or audio- or videotape recording of the subject.

- For clarity, discuss procedures in chronological order (i.e., in the same order that the subject would undergo them), and use separate paragraphs with numbers or bullets for each procedure description.
 - If a researcher is to seek data about the subject indirectly, such as inspecting private records, describe the data and how it will be obtained.
6. Benefits:
- Provide a clear description of any direct benefits to the subject and/or “general” benefits to others (e.g., groups of subjects/patients, society) that may reasonably be expected from the research.
 - If no direct benefit to the individual subject is anticipated, state this.
 - *Note: Compensation/payment for participation is not considered a “benefit,” but should be described instead in its own section (see “Compensation/Payment” below).*
7. Risks/Discomforts:
- Provide a clear description of any reasonably foreseeable risks or discomforts (physical, psychological, or social) to the subject, noting probability and magnitude of potential harm.
 - Discuss measures that will be taken to minimize risks/discomforts.
 - If appropriate, indicate any procedures that may involve risks to the subject (or embryo or fetus) that are currently unforeseeable/unknown.
 - If appropriate, note that the researchers will inform subjects about any significant new findings developed during the course of the research which may relate to their willingness to continue participation in the study.
 - Include risk of breach of confidentiality, and refer subject to next section for more detail.
8. Confidentiality:
- Note: See CPHS website for [Data Security Policy](#) before completing this section.*
- Provide an explanation of the extent to which the confidentiality of private data identifying the subject will be maintained. Since complete confidentiality of research data cannot be guaranteed, avoid any wording that implies such assurance. Instead, use language such as:

Your study data will be handled as confidentially as possible. If results of this study are published or presented, individual names and other personally identifiable information will not be used.

Explain how researcher will minimize the risks to confidentiality (e.g., storage of data, coding, encryption, limited access to study records, etc. should be described).

Also, *if applicable*, indicate any organizations that may look at or copy research records, e.g., study sponsor, FDA, etc. (*Note: Although FDA usually will not record individually identifiable data, it does have this authority. For FDA-regulated studies, the consent form must include a statement about FDA access to research records.*)
 - If the researcher wishes to retain the human subjects data after the immediate project is completed for possible use in future projects by the researcher or others, this should be clearly discussed.
 - As applicable, address special confidentiality issues pertaining to use of photographs, audiotapes, or videotapes; HIPAA-related data; reportable information; Certificate of Confidentiality; etc.

9. Alternatives:

If applicable, state appropriate alternative procedures or courses of treatment that might be advantageous to the subject.

10. Discontinuing Study Participation:

- If appropriate, indicate if there could be negative consequences or restrictions should a subject decide to withdraw from the research, and describe procedures for stopping participation in a safe/orderly manner.
- If appropriate, describe circumstances under which the subject's participation may be ended by the researcher, regardless of subject's consent (e.g., if the researcher believes it is in their best interest, if the subject does not follow the study rules, if the study is stopped).

11. Compensation/Payment of Subjects:

Describe any compensation/payment to be offered subjects, including amount, type (monetary or non-monetary), terms, and schedule by which it will be provided.

12. Costs to Subjects:

If appropriate, describe any costs/charges which subjects or their insurance carriers will be expected to pay. If there are no costs to subjects or their insurers, this may be stated here.

13. Treatment and Compensation for Injury:

If the study involves more than minimal risk, the consent form must include information regarding availability of medical treatment and compensation for the costs of such treatment if injury occurs. The following statement, in accordance with University of California policy, must be used:

It is important that you promptly tell the researcher [*investigator's name*], if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at [*telephone number*].

If you are injured as a result of taking part in this study, University of California will provide necessary medical treatment. The costs of the treatment may be billed to your insurer just like other medical costs, or covered by the University of California or the study sponsor [*sponsor name*], depending upon a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information, call OPHS at (510) 642-7461.

14. Voluntary Nature of Research Participation:

The consent materials must clearly state that *participation in research is voluntary*, and that the individual is free to refuse participation altogether or to discontinue it at any time without penalty or loss of benefits or services to which s/he is otherwise entitled.

15. Questions:

The form must include contact information to subjects in case of any questions about the study or about their rights as a research subject. Provide the telephone number(s) of the researcher(s), as well as contact information for the OPHS (see above) should the subject wish to speak to someone other than the researchers about study concerns or their rights as a research subject. Note: If the researcher is not within the local calling area of subjects, provisions should be made to allow calling without long distance charges to subjects.

16. Consent/Signature Section:

Unless waiver of signed consent has been requested from the CPHS (see discussion below), the form should end as follows:

- State that the person will be given a copy of the consent form to keep. If applicable, also state that they will be given a copy of the Medical Research Subject's Bill of Rights.
- The form should then indicate that if the individual has considered the information presented and wishes to participate in the study, s/he should indicate agreement by signing the form. Labeled lines for signature and date should be provided.
- Additional lines may be added for signature of parents/guardians, legally authorized representatives, persons obtaining consent, etc., when appropriate.
- Footers which contain the CPHS number (if known) and page numbering (e.g., "Page x of y") are recommended.

C. Obtaining Documented Consent: Except in unusual cases, the researcher must document informed consent by use of a written consent form, including all of the elements described above, to be signed by each person agreeing to participate.

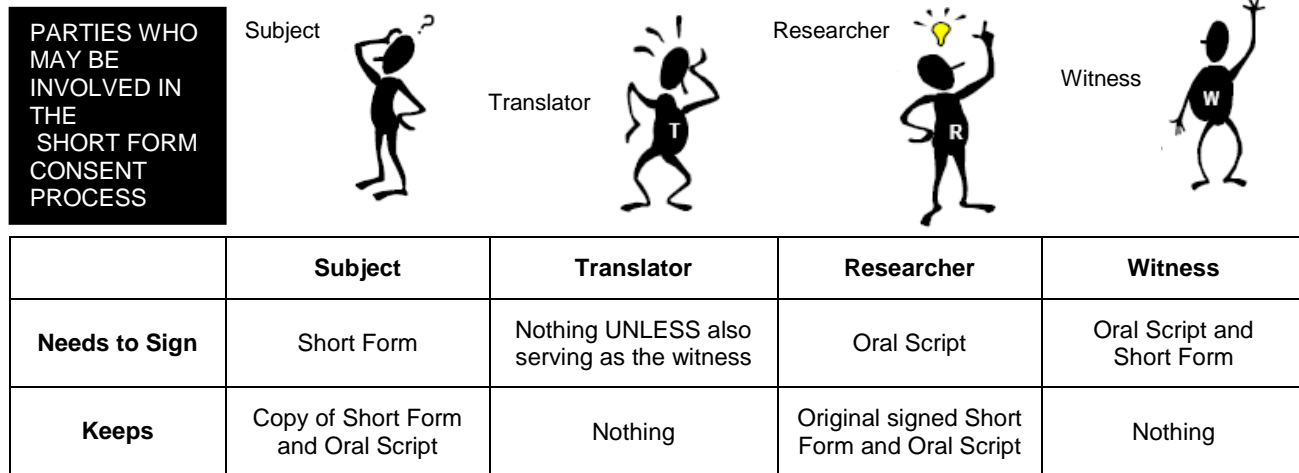
Note: Once approved by the CPHS, the consent form for the study will be stamped with the CPHS number, approval, and expiration date, and returned to the researcher for use in the coming year. *Only copies of the current, stamped version of the consent form(s) may be used with subjects.*

After the consent form is offered, the researcher must give the prospective subject or their legally authorized representative adequate opportunity to read and consider the information presented and express any questions or concerns. If a decision is made to participate, the form will then be signed and dated by the subject or legal representative. A copy of the consent form (and Medical Research Subject's Bill of Rights, if applicable) should be given to the person signing the form. The researcher should safeguard the signed consent forms and retain them for at least three years after the end of the last CPHS approval period.

D. Oral Consent Presentation and the Short Form: As an alternative to the standard written informed consent documents, the required consent information may be presented orally and the subject given a written "Short Form" consent document stating that the elements of informed consent have been presented orally to the subject. When this method is used, the following conditions apply:

- The researcher must have an Oral Script of the consent information to be presented orally.
- The oral presentation and the Short Form must be in the subject's native language.
- A witness to the oral presentation is required. The witness must sign both the Short Form document and a copy of the Oral Script. If an interpreter/translator will be employed to assist with the consent process, the translator may serve as the witness. A researcher may not serve as the witness.
- The subject must sign the Short Form. Adult subjects who are competent to provide consent, but are illiterate or unable to talk or write, may indicate their agreement to participate by making their mark (e.g. an X or a thumbprint) on the Short Form, when consistent with applicable local law.
- The person obtaining consent (e.g., the researcher) must sign a copy of the Oral Script. The person obtaining consent may not also serve as a witness.
- These consent documents (Short Form and Oral Script) with original signatures must be retained by the researcher. The subject must be given copies of the Short Form and the Oral Script to keep.

The CPHS application should provide a detailed description of the informed consent process, including who will conduct the oral presentation, who will serve as the witness, and whether or not an interpreter/translator will be used. In addition, the researcher should submit for review both English and foreign language versions of the Short Form, along with his or her affirmation of the accuracy of the translations, and an English version the Oral Script.



E. Waiver of Informed Consent: According to HHS federal regulations (45 CFR 46.116(c)), the CPHS may waive the requirement to obtain informed consent, or it may approve a consent procedure that alters some of the elements of informed consent described above.

However, the CPHS must first be satisfied that:

- 1) The research
 - (a) presents no risks of harm, considering probability and magnitude, greater than those ordinarily encountered in daily life or during the performance of routine examinations or tests; and
 - (b) the waiver or alteration will not adversely affect the rights and welfare of the subjects; and
 - (c) the research could not practicably be carried out without the waiver or alteration; and
 - (d) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

OR

- 2) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) programs under the Social Security Act, or other public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

Note: Consent waiver is not allowed for FDA-regulated research.

Deception in research: Informed consent implies that subjects will be correctly informed and not deliberately misled about a study. In certain cases, the CPHS may allow a researcher to give subjects incomplete or even misleading information about the nature of the research. However, to obtain such approval, the researcher must justify use of incomplete disclosure or active deception according to the criteria above for waiving some or all elements of informed consent. Usually, the researcher will be required to give the subject a debriefing form after study participation to correct the misleading information, and in certain cases, will need to offer the subjects an opportunity to reaffirm or withdraw their consent for use of data obtained in this manner.

Note: See CPHS website for [Guidelines on Deception and Incomplete Disclosure in Research](#).

F. Waiver of Documented Consent: Also according to federal regulations (45 CFR 46.117(c)), the CPHS may waive the requirement for the researcher to obtain documented (i.e., signed/written) consent for some or all subjects. However, the researcher must first satisfy the CPHS that either:

1. The only record in the researcher's possession linking the subject and the research would be the consent document, and the principal risk of the study would be potential harm resulting from a breach of confidentiality. Each subject must be asked whether they want documentation linking them with the research, and the subject's wishes will govern; or
2. The research presents no risks of harm, considering probability and magnitude, greater than those ordinarily encountered in daily life or during the performance of routine examinations or tests, and the research involves no procedures for which written consent is normally required outside of a research context.

***Note:** When the documentation requirements are waived, the CPHS will usually require that the researcher provide subjects with a written or oral statement containing the elements of informed consent, as appropriate.*

.....*For more detail and examples, see [Consent Form Samples/Templates](#).*