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| P&P: IC 701 Version No: 1.2 Effective Date: 6/1/2013 | GENERAL REQUIREMENTS AND DOCUMENTATION FOR INFORMED CONSENT | Supercedes: CPHS Policies and Procedures 9/1/2007 |
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1. POLICY

As set forth in the governing principles of The Belmont Report and codified in federal human research regulations, investigators who wish to involve human subjects in research are obliged to seek their voluntary and informed participation through an informed consent process. Securing and maintaining consent is an ongoing process that begins with recruitment and continues through the end of the participants' involvement in the study.

Except as described in IC 702 ("Waivers of Informed Consent"), no investigator may involve a human being as a research subject unless he/she has obtained legally effective informed consent of the subject or the subject's legally authorized representative. Consent must be sought only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

As part of this process, the IRB requires documentation of informed consent by use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative, unless an alternative method for obtaining informed consent is approved by the IRB (as below). (Note: Obtaining assent and parental permission for research involving children/minors is discussed separately in IC 703, "Assent and Parental/Guardian Permission").

Specific Policies

1.1 The Consent Form May Be Either of the Following:

- A. A written consent document that embodies the elements of informed consent described in 45 CFR 46.116(a) and/or 21 CFR 50.25. This form may be read to the subject or the subject's legally authorized representative, but in any event, the Investigator shall allow adequate opportunity for the form to be read to or by the subject or representative before it is signed. The subject or representative must also be given a copy of the form.
- B. A "short form" written consent document stating that the required elements of informed consent have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be an impartial witness to the oral presentation (i.e., the witness cannot be the person obtaining the consent). The IRB must also approve a written summary of what is to be said to the subject or representative. The subject or the representative signs only the short form itself. However, the witness shall sign both the short form and a copy of the summary, and the person obtaining the consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative in addition to a copy of the short form.

The "short form" method may be used in circumstances where oral presentation of informed consent is preferable or necessary, e.g., subjects are illiterate in English or their native language.

1.2 Required Elements of Informed Consent

- A. A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental.
- B. A description of any reasonably foreseeable risks or discomforts to the subject.
- C. A description of any benefits to the subject or to others that may reasonably be expected from the research.
- D. A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject.
- E. A statement that describes the extent to which, if any, confidentiality of records identifying the subject will be maintained, and if applicable, notes the possibility that the FDA and/or other agencies or individuals may inspect the records.
- F. For research involving more than minimal risk, an explanation as to whether any compensation is provided 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.
- G. 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.
- H. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

1.3 Additional Elements

When appropriate, one or more of the following elements of information shall also be provided to each subject:

- A. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus if the subject is or may become pregnant) which are currently unforeseeable.
- B. Anticipated circumstances under which the subject's participation may be terminated by the Investigator without regard to the subject's consent.
- C. Any additional costs to the subject that may result from participation in the research.
- D. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
- E. 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.
- F. The approximate number of subjects involved in the study.

1.4 Other Requirements

A. Understandable language: The information presented in the consent documents must be in language likely to be understood by the subject population. Technical and scientific terms should be adequately explained using common or lay terminology.

In general, forms should be written at no higher than an eighth-grade reading level when the target population is adults.

B. No exculpatory language: Informed consent documents may not contain any exculpatory language through which the subject is made to waive or appear to waive legal rights, or release or appear to release the Investigator, the Sponsor, or the University of California, Berkeley from liability for negligence.

C. FDA-regulated test articles: For all research involving test articles regulated by the FDA, informed consent documents must include a statement that the purpose of the study includes evaluation of both the safety and the effectiveness of the test article. The consent form must also include a statement that the FDA has access to the subject's medical records.

1.5 Documentation of Informed Consent

Each subject or his or her legally authorized representative must sign and date a copy of the current IRB-approved consent form prior to enrollment or any participation in any phase of the study, unless the requirement for consent or documentation thereof is waived by the IRB. This consent form with original signatures must be retained by the Investigator per the UC Records Retention Policy. The subject and/or his or her legally authorized representative must also be given a copy of the document.

The IRB may approve procedures for documentation of informed consent that involve: (a) a written consent form signed by the subject or his/her legally authorized representative; (b) a short form written consent form and summary with oral presentation; or (c) in limited circumstances, waiver of signed written consent form. Each of these three options is described in detail below. It is the responsibility of the IRB to determine which of the procedures described below is appropriate for documenting informed consent in research protocols that it reviews.

1.5.1 Written consent form signed by subject or legally authorized representative. In most circumstances, the IRB will require that informed consent is documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. The Investigator should allow adequate opportunity for the form to be read to or by the subject or representative before it is signed. A copy of the document must be given to the participant and/or the person signing the form.

1.5.2 The written informed consent document should embody, in language understandable to the subject, all the elements necessary for legally effective informed consent (see sections 1.2 and 1.3 above).

1.5.3 Subjects who do not understand English should be presented with an informed consent document written in a language understandable to them. See section 1.7.

1.6 Oral Presentation Using Short Form

As an alternative to standard written informed consent documents, oral presentation of informed consent information may be used.

In such cases, the subject must be provided with both:

- A short form written consent document stating that the elements of informed consent have been presented orally to the subject or the subject's legally authorized representative; and
- A written summary of the information that is presented orally.

1.6.1 A witness to the oral presentation is required. The witness must sign both the short form written consent document and a copy of the written summary.

1.6.2 The subject or the legally authorized representative must sign the short form written consent document.

1.6.3 The person obtaining consent (e.g., the Investigator) must sign a copy of the written summary of the information that is presented orally. The person obtaining consent may not also serve as the witness to the consent.

1.7 Translations for Subjects Who Do Not Speak English

1.7.1 Written Informed Consent: When non-English speaking participants are to be included in a research study, the following conditions must be met:

- (i) The written informed consent document must be translated into a language understandable to the subject; and
- (ii) The investigator must submit foreign language translations of the final, IRB-approved consent documents as soon as these translations are available. Such translated consent documents may be submitted before the final initial approval is issued, or may be submitted for expedited review as a response to IRB conditional approval (in the case of short form documents, see 1.7.2 below) or as an amendment after initial approval of the research and English consent documents. In any case, the investigator must affirm the accuracy of the translations; based on the investigator's affirmation, the IRB or Chair/ Designee (as appropriate) will approve the translated documents. All approved informed consent, parental permission, and assent documents (English and foreign language) will be made available to the investigator.

1.7.2 Oral Presentation with Short Form: Where informed consent is documented using this short form procedure (see section 1.6 above) with non-English speaking subjects, the following conditions must be met:

- (i) the oral presentation and the short form written informed consent document should be in a language understandable to the subject;
- (ii) the IRB-approved English language informed consent document may serve as the summary; and
- (iii) the witness should be fluent in both English and the language of the subject.

At the time of consent, (i) the short form document should be signed by the subject or the subject's legally authorized representative; (ii) the summary should be signed by the person obtaining consent as authorized under the protocol; and (iii) the short form document and the summary should be signed by the witness. When the person obtaining consent is assisted by a translator, the translator may serve as the witness.

The IRB must receive all translated versions of the short form document as a condition of approval. The investigator should also submit any translations of other final, IRB-approved consent documents (e.g., the summary) for the IRB files as soon as these translations are available. As appropriate, the investigator must affirm the accuracy of these translations.

1.8 Consent Documentation with Subjects Who Are Illiterate or Unable to Talk or Write

1.8.1 The IRB may approve alternate procedures for documenting informed consent when the prospective subject speaks and understands English (or the language in which the consent process and forms are approved), but does not read and write it. Such individuals may indicate agreement to participate by "making their mark" on the consent document, when consistent with applicable state and/or local law.

1.8.2 The IRB may approve alternate procedures for documenting informed consent when the prospective subject understands and comprehends spoken English (or the language in which the consent process and forms are approved), but is physically unable to talk, write, or "make their mark." Such individuals may be entered into a study if they are competent and able to indicate agreement or disagreement to study participation by other means. The consent form should document the method used for communication and the specific means by which the prospective subject communicated agreement to participate in the study. An impartial third party should witness the entire consent process and sign the consent document(s); a videotape recording of the consent process may also be recommended.

1.9 Waiver of Documentation

The IRB may waive the requirement for the Investigator to obtain a signed consent form for some or all subjects if the IRB finds either:

- That the only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality, including knowledge of an individual's participation in the study. (In this case, each subject will be asked whether he/she wants documentation linking him/her with the research, and the subject's wishes will govern); or
- That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

1.9.1 In cases in which the documentation requirement is waived, the IRB may require the Investigator to provide subjects with a written statement regarding the research.

- 1.9.2 The IRB may waive documentation of parental or guardian permission in research involving children using the same criteria as above.

For situations in which the IRB may waive or alter some or all of the elements of the written informed consent, refer to IC 702 (“Waivers of Informed Consent”).

2. SCOPE

These policies and procedures apply to all non-exempt research submitted to the UC Berkeley IRB.

3. RESPONSIBILITY

The OPHS Staff are responsible for screening/pre-reviewing all informed consent documents and for communicating with Investigators to bring documents into compliance, before and/or after full Committee/ IRB Chair review. The IRB members and/or IRB Chair or designee are responsible for final review and approval of consent documents.

4. PROCESS OVERVIEW

An OPHS administrative staff member will pre-review all applications to ensure that the consent form documents adhere to the Consent Form Guidelines. Staff will notify the Investigator of any omissions or necessary corrections before and/or after review, as appropriate, by the full IRB (for applications requiring full Committee review) or IRB Chair or designee (for applications or responses requiring expedited review.)

The Consent Form document will be evaluated on the basis of both the CPHS Informed Consent Guidelines and the respective research protocol, including special attention to such issues as readability, appropriate language, and completeness of relevant information. The IRB members and/or IRB Chair or designee will subsequently confirm, reject, or add to this evaluation, and will give final approval as per the type of application.

After the application is approved, all approved informed consent, parental permission, and assent documents (English and foreign language) will be made available to the Investigator along with the protocol approval letter. While the practice of approval stamping consent documents has generally been discontinued (effective 3/1/2013), consent documents may be approval-stamped by OPHS staff upon the request of the investigator.

Any foreign language translations of approved consent documents must be submitted, either with initial application materials, as responsive materials to a conditional approval by the IRB, or as an amendment after initial approval of the research and English consent documents. For any translated consent documents, the investigator must affirm the accuracy of the translations.

5. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.116, 46.117

21 CFR 50

FDA Information Sheets, 1998