

Obtaining Informed Consent

Informed consent will be sought from all prospective participants (or their legally authorized representatives) unless waived by the IRB. Investigators should be sensitive to the possible need of an interpreter- translator for subjects who do not speak English and/or prepare a consent form in the person's native language. The IRB may waive the requirement of a signed consent form if:

- (a) This consent form is the only record linking the subject with the research and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
- (b) The research presents no more than minimal risk of harm to subjects, involving no procedures for which written consent is normally required outside the context of the research. Such a waiver might be appropriate where the research involves minimal risk, the rights and welfare of the subjects are not adversely affected, and the research would not be feasible without the waiver.

A researcher should not use deception unless it has been carefully determined that deception is the only way to accomplish the end and that the deception is justified by the study's potential benefit. The following must be maintained:

- (a) A researcher should never deceive participants about significant aspects that would affect their willingness to participate, such as physical risks, discomfort, or unpleasant emotional experience.
- (b) Deception necessary to the study's design must be explained to participants as early as is feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the research (Information on deception is from the APA's ethical standards).

It is realized that some research might be hindered if the participant fully understands the purpose and procedures before participating. If deception is necessary, there are two elements that must be insured.

- (a) There is no reason to believe that the participant would not consent to participate, if had received full disclosure prior to beginning the research.
- (b) There is a debriefing following the research that completely informs the participant of the purpose and procedures and the reason for the initial deception.

Basic Elements of Informed Consent

Informed consent is the agreement obtained from a subject, or from an authorized representative, for the subject's participation in an activity. The agreement, written or oral, entered into by the subject, may include no exculpatory language through which the subject is made to waive, or to appear to waive, any of the subject's legal rights, or to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Written Consent Document

Documented informed consent will consist of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form. The signed consent forms and summaries shall be kept in the investigator's file available upon request to the HPRB. (They should be maintained by the investigator for 3 years.)

- (a) A written consent document that embodies the elements of informed consent. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or
- (b) 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. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining 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."

Eight Elements

The basic elements of informed consent are:

Purpose

- (1) A statement that identifies the exercise as a research activity, provides an explanation of the purpose(s) of the research, estimates the duration of the subject's participation, details procedures to be followed, and identifies any procedures which are experimental.

Description of Risk

- (2) A description of any reasonably foreseeable risks or discomforts to the subject;

Benefits

- (3) A description of any benefits to the subject or to others which may reasonably be expected from the research; (personally and to society)

Disclosure of Alternate Procedures (not usually applicable to PLU research)

- (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

Statement of Confidentiality

- (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

Statement Procedures For Greater Than Minimal Risk

- (6) 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 following statement might be used:

“I understand the University does not provide a research subject with compensation or medical treatment in the event the subject is injured as a result of participation in the research project.”

Subjects’ Right Relative To Injury (Physical, Emotional or Social)

- (7) An explanation of whom to contact for answers to pertinent questions about: a) the research, b) the subject’s rights, and c) the person to contact in the event of a research-related injury. A statement such as the following might be used:

“Questions about the research, my rights, or research-related injuries should be directed to (PI name, supervising faculty, & telephone number for both).”

Statement That Participation is Voluntary

- (8) 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 that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Note:

If there will be collection of body fluids, an additional statement within the informed consent must be included. This addition is in Collection of Body Fluids document.

