Basic Elements of Informed Consent Includes:

A. A statement that the proposed activity involves research, and an explanation of the research purpose, including the larger social purpose, if applicable. (When elements of purpose cannot be disclosed without biasing the behavior of subject in a way that would invalidate the objectives of the study, the investigator may request that modified informed consent be obtained.) The investigator's name and affiliation with California State University, Fresno should also be provided.

B. A fair explanation of the procedures, including frequency, duration, site of administration, and identification of any procedures that are experimental. The explanation of the procedures and purposes must be given in terms comprehensible to the intended subject, e.g., 5cc = I teaspoon. It is often useful to indicate the immediate purpose of procedures on the subjects.

C. A description of any reasonably forseeable risks or discomforts to the subject. It is appropriate to estimate the degree of risk and to be especially candid about high risk procedures.

D. A description of any benefits to the subject or to others which may reasonably be expected from the research. A distinction should be made between personal benefits and social benefits.

E. A disclosure of any appropriate alternative procedures that might be advantageous for the subject, including their risks and benefits. Disclosure of alternative procedures is only applicable in certain circumstances, particularly when a new diagnostic or therapeutic procedure is being used. The discussion of the alternative must be fair and should attempt to balance the alternatives against the experimental therapy or procedures. The risks and benefits of the alternatives should, therefore, be discussed.

F. A statement describing the extent to which confidentiality of the subject will be maintained.

G. When applicable, the amount and nature of compensation to be given to the subject.

H. A statement that participation is voluntary; refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled. If the subject decides to participate, he or she is free to discontinue participation at any time without penalty.

I. An offer to answer questions, with a resource to contact for later questions regarding the research.

Additional Elements of Informed Consent

When required by the CPHS, the research investigator must provide one or more of the following elements of information to the subjects:

A. How the subject's name and address or phone number were obtained.

B. The possibility that the particular treatment or procedure may involve risks to the subject (or the embryo or fetus, if the subject is or may become pregnant) that are currently unforseeable.

C. Description of compensation for participation and conditions under which it will be paid.

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

E. Consequences of a subject's decision to withdraw from the research, and circumstances under which the subject's participation may be terminated by the research investigator without regard to the subject's consent.

F. 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.

G. The approximate number of subjects involved in the study.

Informed Consent as a Process

Informed consent should not be thought of as a form to be signed, but as an ongoing educational process between the research investigator and the prospective subject. The investigator should attempt to view the activity from the subject's perspective to consider what the subject might want to know before deciding whether or not to participate in the research. Information must be presented to the prospective subject in language he or she can easily understand and a dialog of questions and explanations should be encouraged. The investigator should talk with the subject until he or she feels confident that the subject understands what is being asked.

If the information is so complex or possibly disturbing that it may require some time to be absorbed and evaluated by the subject, the investigator should consider using a multi-stage consent process. The investigator might present the information and discuss the issues on more than one occasion or allow a period of time to elapse between presenting the information and requesting a signature on the consent form. For procedures that are very stressful or otherwise involve substantial risk, the investigator might also ask for reaffirmation of the subject's consent at various stages of his or her participation.

Cross-Cultural Consideration

Informed consent should be obtained in the native language of the subject if English is not readily understood. If the research is done in cultures where signed statements are mistrusted, or where the concept of experimentation itself is unfamiliar, the investigator's protocol should clearly indicate how the project will be explained, how the consent of the subject will be obtained, and who will validate the act of consent.

Oral Consent

If approval for the use of oral consent is sought, the information to be conveyed to the potential subjects must be submitted to the CPHS with the protocol. The rationale for the use of the oral consent procedure rather than the written consent procedure should be included.

Exculpatory Clauses

No consent form may contain exculpatory language through which the subject is made to waive, or appear to waive, any of his or her legal rights, or to release the institution or its agents from liability for negligence.