REQUIRED ELEMENTS OF CONSENT

The consent process, whether written or oral, must cover all of these basic elements unless a waiver is formally requested. Use this checklist to construct your Consent Form document.

√	Element
1	A statement that the study involves research
2	A statement of who is responsible for the research including the name and phone number of the Principal Investigator
3	An explanation of the purpose of the research
4	A description of the procedures to be followed
5	The expected duration of the subject's participation
6	A description of any reasonably foreseeable risks or discomforts to the subject. If there are no such risks or discomforts, the consent form should so state
7	A description of any benefits to the subject or to others which may be reasonably expected from the research. If there are no such benefits, the consent form should so state
8	A statement describing the extent to which confidentiality of records identifying the subject will be maintained
9	A statement that participation is voluntary, that refusal to participate involves 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
10	The following statement about subjects' rights: "Dr. (Principal Investigator) will answer any questions you have about the study. You can call (phone number) or email (email address). Questions can also be directed to the Human Research Protection Program (HRPP), Office of the Vice President for Research, Texas Tech University, Lubbock, Texas 79409, 806-742-2064."
11	A statement about the expiration date of the project's approval: "This consent form is not valid after (expiration date)." The expiration date is the anniversary of last day of the month preceding the approval. The letter informing the investigator of the approval of a proposal specifies the date of expiration.

Additional elements of consent as appropriate.

Additional elements of informed consent that must be included to meet the standard of fully informed consent on the part of research subjects may involve items such as the following:

√	Element
A	For research involving more than minimal risk: An explanation concerning compensation for research-related injury as follows: "If this research project causes injury (physical, psychological, social, economic, legal, etc.), Texas Tech University or the Student Health Services, may not be able to treat your injury. You will have to pay for treatment from your own insurance. The University does not have insurance to cover such injuries. More information about these matters may be obtained from Dr. Alice Young, Associate Vice President, Research Integrity, Office of the Vice President for Research, (806) 742-3905, 355 Administration Building, Texas Tech University, Lubbock, Texas, 79409." If there is a specific plan for liability, it should be described in place of this statement.
B	For research that involves any procedures or treatments that a subject might reasonably construe to be therapeutic: A description of any procedures that are experimental and a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
C	A statement that the particular treatment or procedure may involve risks to the subject (or to an embryo or fetus if the subject is pregnant) which are currently unforeseeable.
D	Anticipated circumstances under which the participation may be terminated by the investigator without regard to the subject's consent
E	Any additional costs to the subject that may result from participation in the research.
F	The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
G	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.
H	The approximate number of subjects involved in the study.