

Required Elements of consent

The consent process, whether written or oral, must cover all of these basic elements unless a waiver is formally requested.

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 none, 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. For questions about your rights as a subject or about injuries caused by this research, contact the Texas Tech University Institutional Review Board for the Protection of Human Subjects, Office of Research Services, Texas Tech University, Lubbock, Texas 79409. Or you can call (806) 742-3884."
11. _____ The following statement about the expiration 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 (see Timing of review in section XIII of Policies and Procedures). 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:

12. _____ 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, financial, etc.), Texas Tech University or the Student Health Center, 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. Kathleen Harris, Assistant Vice President for Research, (806) 742-3884, Room 203 Holden Hall, Texas Tech University, Lubbock, Texas, 79409." If there is a specific plan for liability, it should be described in place of this standard statement.
13. _____ 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.
14. _____ 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.
15. _____ Anticipated circumstances under which the participation may be terminated by the investigator without regard to the subject's consent.
16. _____ Any additional costs to the subject that may result from participation in the research.
17. _____ The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
18. _____ 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.
19. _____ The approximate number of subjects involved in the study.