

CONSENT FORM - Adults INSTRUCTIONS

The purpose of a consent form is to help the investigator protect *subjects* by *informing* them about the research and their rights as human subjects. Thus, it takes two components in achieving this goal: the consent process and the consent form.

A written consent form must contain all the required information (see Elements of Consent checklist in Appendix L) and it must be capable of being fully understood by the individuals expected to read it. All the relevant information should be included. It is not sufficient to say, “Dr. Jones has explained” such things as the procedure or risks and discomforts. You should put these explanations in the written consent form or else use the short form consent that requires a script of the accompanying oral presentation about the procedure, risks, etc. One way or the other, the IRB needs to know *what* the subjects will be informed of, not merely that they *will* be informed. Technical material and the purpose of the study must be explained in lay terms. Procedures should be explained from the point of view of what will happen to the subject in the course of the study.

A general rule of thumb used by federal regulators is that consent forms aimed at the general public should be written at a 7th grade reading level. Adjustments up or down from that standard can be made depending on the target population of subjects. Short sentences and the use of smaller words help to achieve lower reading levels. The Flesch-Kincaid grade level estimate is available by clicking on Tools, Options, Spelling & Grammar in Microsoft Word. It may be helpful but is only an aid for writing at the appropriate level. Common sense is sometimes a better guide. The example below is a consent form written for college students. The Flesch-Kincaid grade level is 6.7. The link below may be useful in writing consent forms:

<http://www.plainlanguage.gov>

The document is not supposed to be a legal document that somehow protects the *researcher*. In fact, courts have ruled that a signed consent form that is too difficult for the subject to understand neither constitutes consent nor protects the investigator and the institution from liability. Therefore, pseudo-legal language such as “hereby”, “aforementioned”, etc should be avoided on the grounds that it detracts from communication.

Federal regulators also suggest that, in order to facilitate communication, consent forms need to be written in the second person and avoid phrases such as “I understand that...” because they add nothing meaningful beyond the subject’s signature.

Texas Tech University does not have a model consent form and the consent forms below are just examples. The IRB believes that subjects’ rights will be better protected if investigators have to think about the best way to inform subjects rather than simply filling out a form.

Any format is acceptable as long as it serves its intended purpose and includes the elements of consent. Investigators should craft consent forms that clearly include the elements of consent but which are specific to their own research program and to particular projects. It may be a

good idea for each researcher to create a model consent form or template that can be modified for specific projects.

The consent process is a critical component in achieving understanding of the research and the participant's involvement throughout the study. There are different methods of conducting the consent process and the researcher can determine the best method based upon the project's procedures. The end result of the consent process should also be two-fold: (1) the participant's understanding of their involvement in the research project and (2) the researcher's assurance that the participant has been properly informed and comprehended the research requirements involved.

One copy of the consent form must be given to the subject and one copy must be retained by the investigator. The investigator must keep consent forms for a period of three years after the termination of the IRB approval. Expiration dates on consent forms change when annual reviews are conducted and approved. Investigators should be cognizant of consent form expiration dates.