INFORMED CONSENT
INSTRUCTIONS

Informed consent is a process, not just a form!

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. Before proceeding any further, closely read the TIPS ON INFORMED CONSENT published by the Office for Protection from Research Risks.

A written consent form must contain all the required information (see Informed Consent in Appendix V in the WTAMU IRB Policies and Procedures and the Informed Consent Checklist provided on the OHRP website) 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. Mendez has explained” such things as the procedure or risks and discomforts. You should put these explanations in the written consent form or else use a short form consent that requires a script of the accompanying oral presentation about the procedure, risks, etc. The IRB must know what the subjects will be informed of, and how they will be informed of it—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. The Office for Human Research Protections (OHRP) provides detailed information about informed consent. The WTAMU IRB urges all human subjects researchers to explore this information prior to developing an informed consent process and form.

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. Guidance for selection of language to use on consent forms for the general public is located at http://www.plainlanguage.gov/.

The informed consent 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.

West Texas A&M University does not have a “model” consent form per se, but does have sample consent forms located in Appendix VI of the IRB Policies and Procedures. The IRB believes that subjects’ rights will be better protected if investigators think through the best way to inform subjects rather than simply filling out a university-generated generic 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 and are specific to their own research program and to particular 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 his/her 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.
The purpose of a consent form for minors, called an Assent Form, is to help the investigator protect subjects by informing them about the research and their rights as human subjects, even as a minor. There are four components in achieving this goal when research involves minors: 1) the consent process and 2) the consent form for parents; and 3) the consent process and 4) assent form for minors. A minor in the State of Texas is an individual under the age of 18.