Consent Form Guidance

Informed consent is a process, not just a form. The procedures used in obtaining informed consent should be designed to educate the participant population in terms that they can understand.

The consent process is necessary to assure that participants are fully informed when deciding to voluntarily participate in a research project of any type. An important point to remember when writing a consent document is to keep in short and simple. Include necessary information, but do not burden the participant with information that is not needed. The longer the consent document, the less likely the participant will be able to read it in its entirety.

Consent documents should be written in a language appropriate to the participant population. For clinical trials, one should assume that the subject knows no medical terminology and all medical terms should be listed in simple non-medical words. The only exception to this might be a study in a population with a long standing medical condition, where they are knowledgeable of this terminology.

The consent document is primarily used as a teaching tool, not as a legal instrument. Federal regulatory agencies (such as the FDA and OPRR) prefer that the consent form be written in second person (you/your) as this leads towards an interactive discussion and appears less coercive.

OUHSC IRB requires that consent forms be completed using the Main Consent Template. This includes research that is industry sponsored. If you receive a sample consent from your sponsor, it is recommended that you begin with the OUHSC consent template, and add any sponsor-required information. The final consent form should be a clean document, void of any tracked changes or comments, when you submit your Initial Submission Packet to the IRB.

Federal Regulations require that certain information be included in all research consent documents. These informational items are as follows:

- Statement that the study involves research
- Explanation of the purposes of the research
- Duration of the subject's participation
- Identification of any experimental procedures and/or drugs
- Description of procedures to be followed
- Reasonably foreseeable risks or discomforts
- Direct benefits reasonably expected
- Appropriate alternative procedures or treatments
- Extent of confidentiality of records
- Availability of compensation
- Information regarding availability of medical treatment
- Who to contact with questions about the research project
- Who to contact with questions about rights as a research subject
- Statement that participation is voluntary and refusal to participate will involve no penalty or loss of benefits otherwise entitled to and that subject may discontinue participation at any time without penalty or loss of benefits

This information **MUST** be included in all consent documents. This includes studies which have no risk or benefit where the alternative is simply to refuse. In cases such as this, you may combine several categories into one statement. An example would be, "There are no risks, benefits or costs to you for participating. Your alternative is not to participate in this study."

Other information which should be included when applicable to a particular study is as follows:

- Statement that participation may involve other unforeseeable risks
- Circumstances under which participation may be terminated by the investigator
- Additional costs to the subject
- Consequences of early withdrawal
- Statement that significant new findings will be provided to subject

The final paragraph and signature lines should not be alone on the final page of the consent as it could appear that the remainder of the document was not included when signature was obtained. Either reformat the consent form to include a portion of the previous paragraph on the last page or repeat the title of the study and state that the subject has read the previous number of pages.

To reiterate statements made above, please review the paragraph below before you submit to the IRB:

> OUHSC IRB requires that consent forms be completed and submitted on the HSC Main Consent Template. This includes research that is industry sponsored. If you receive a sample consent from your sponsor, it is recommended that you begin with the HSC consent template, and add any sponsor-required information to the HSC template.
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> Additionally, the final draft of a consent form should be a clean document, void of any tracked changes or comments when submitting for IRB review.