

# **Basic Elements of Informed Consent**

## **General Informed Consent Considerations**

Investigators should seek consent only under circumstances that provide the prospective participants sufficient opportunity to consider whether to participate, and that minimize the possibility of coercion or undue influence. Consent and information forms must be written in language that is understandable and clear to potential participants. The consent process may not include exculpatory statements through which participants waive or appear to waive any legal rights, or release or appear to release the investigator, sponsor, institution, or agents from liability for negligence.

## **Basic Elements of Informed Consent**

As you develop your consent form or procedure, please include the following information.

1. State that the study involves research.
2. Explain the purposes of the research and the expected duration of the participants' participation.
3. Describe the procedures that directly involve human participants, and identify of any procedures that are experimental.
4. Describe any foreseeable risks or discomforts to participants.
5. Describe any benefits to participants or to others that may reasonably be expected from the research.
6. Disclose alternative procedures or courses of treatment, if any, which might be advantageous to participants.
7. Describe the extent to which confidentiality of records identifying participants will be maintained, where the records will be stored, and who will have access to the records.
8. For research involving more than minimal risk, explain whether any compensation or medical treatments are available if injury occurs. If compensation or treatments are available, they should be described. The procedures for obtaining additional compensation/treatment information should be stated.
9. Identify the persons participants can contact for answers to pertinent questions about the research, and participants' rights.

10. State that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which participants are otherwise entitled, and also that participants may discontinue participation at any time without penalty or loss of benefits to which they are otherwise entitled.

### **Additional Elements of Informed Consent**

The following additional elements of informed consent may be required.

1. A statement that the particular treatment or procedure may involve risks to the participant that are unforeseeable.
2. Anticipated circumstances under which a participant's participation may be terminated by the investigator without regard to the participant's consent.
3. Any additional costs to the participant that may result from participation in the research.
4. The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant.
5. A statement that significant new findings developed during the course of the research that may relate to the participant's willingness to continue participation will be provided to the participant.
6. The approximate number of participants involved in the study.

### **Contacts for Further Information**

If you have any questions about preparing an informed consent form or procedure, please check with your Departmental Review Committee or the Office of Research Compliance Officer at (865) 974-3466.