

Institutional Review Board

Aurora University

Elements of Informed Consent

Informed Consent Considerations

Investigators should seek consent 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 (in compliance with Protection of Human Subjects Federal Regulations 45 CFR 46, 2009).

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 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, how long they will be stored (at least 3 years) 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 who participants can contact for answers to pertinent questions about the research, and participants' rights including the student advisor, the IRB chair, the primary researchers, and a resource in case of discomfort (AU Counseling Center).
10. State that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which participants are otherwise entitled, and that participants may discontinue participation at any time without penalty or loss of benefits to which they are otherwise entitled.
11. Include signature lines for consent as well as audiotaping consent signature line, if applicable.