



Institutional Review Board

Required Elements of Informed Consent **The Information that MUST be provided to potential participants of Research**

The informed consent process is one of the primary ethical requirements when conducting research with human participants; it reflects the basic principle of respect for persons. Obtaining informed consent seeks to ensure that potential participants will understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate. The elements of informed consent are mandated in the regulations at 45 CFR 46.116, 38 CFR 16.116, and 21 CFR 50.25.

The consent templates on the Swarthmore IRB website include these required elements. The researcher must adequately address each per the research study design. If the required elements are not adequately stated in the consent document, the IRB will be unable to grant approval for the research. Once approved, only the versions that were included in the approved protocol should be used. Any changes to approved consent documents require IRB approval.

Required Elements:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the participant's participation, a description of the procedures to be followed and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the participant;
3. A description of any benefits to the participant or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;
5. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;
6. For research involving minimal risk, an explanation as to whether any medical treatments or compensation are available if injury occurs and, if so, what they consist of or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and research participant's rights, and whom to contact in the event of a research-related injury to the participant; and
8. A statement that participation is voluntary and refusal to participate will not involve a penalty or loss of benefits to which the participant is otherwise entitled, that the participant may discontinue participation at any time without penalty or loss of benefits to which he/she is otherwise entitled and that the participant will receive a copy of the signed informed consent.