



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 WSU 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 have an IRB stamp should be used. Any changes to approved consent documents require IRB approval and a new IRB stamp prior to use.

Informed consent as a whole must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective participant's understanding of the reasons why one might or might not want to participate.

The prospective participant or Legally Authorized Representative (LAR) must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate and an opportunity to discuss that information.

Key Information:

Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective participant or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

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 more than 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 participants' 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.
9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
 - i. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the participant or the LAR, if this might be a possibility; or
 - ii. A statement that the participant's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Additional Elements:

One or more of the following elements of information, when appropriate shall also be provided to each prospective participant or LAR in the body of the consent form.

1. A statement that the particular treatment or procedure may involve risks to the participant (or the embryo or fetus, if the participant is or may become pregnant) that are currently unforeseeable;
2. Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's or LAR'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 the 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

7. A statement that the participant's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the participant will or will not share in this commercial profit;
8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to participants, and if so, under what conditions; and
9. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).