

General requirements for informed consent [from 45 CFR 46.116]

- Before involving a human subject in research, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.
- An investigator shall seek consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
- The information that is given to the subject or the representative shall be in language understandable to the subject or representative.
- The prospective subject or representative 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.
- The informed consent (and associated documentation) must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or representative 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.
- 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 subject's or representative's understanding of the reasons why one might or might not want to participate.
- No consent may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.
- Any applicable federal, state, or local laws which require additional information to be disclosed to a subject in order for the consent to be legally effective should be followed.
- In addition, the following information should be provided to the subject:
 - statement that the study involves research
 - explanation of the purposes of the research
 - explanation of the expected duration of the subject's participation
 - description of the procedures to be followed
 - identification of any procedures which are experimental
 - description of any reasonably foreseeable risks or discomforts to the subject
 - description of any benefits to the subjects or to others which may reasonably be expected from the research
 - disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
 - statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
 - explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights
 - explanation of whom to contact in the event of a research-related injury to the subject
 - statement that participation is voluntary

- statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled
- statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled
- for research of more than minimal risk, an explanation as to whether any compensation and any medical treatments are available if injury occurs and if so, what they consist of, or where further information may be obtained
- for research involving identifiable private information or identifiable biospecimens:
 - 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 without additional informed consent, if this might be a possibility
 - or -
 - statement that the subject'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.

If you have not requested a waiver or alteration of consent, the above conditions must be upheld.

- When appropriate, the following elements should also be provided to the subject:*
 - statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable
 - anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or representative's consent
 - any additional costs to that subject that may result from participation in the research
 - consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
 - statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject
 - approximate number of subjects involved in the study
 - statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in the commercial profit
 - statement regarding whether any clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions
 - for research involving biospecimens, whether the research will (if known) or might include whole genome sequencing

** Note that the IRB Committee makes the decision regarding appropriateness of the information to be included in the consent form, and in most cases asks that many or all of these "additional" elements be included.*