**45 CFR 46.116 (a) & (b)**

**(a)*General.*** General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements set forth in paragraphs (b) through (d) of this section. Broad consent may be obtained in lieu of informed consent obtained in accordance with paragraphs (b) and (c) of this section only with respect to the storage, maintenance, and secondary [research](https://www.law.cornell.edu/cfr/text/45/46.116) uses of [identifiable private information](https://www.law.cornell.edu/cfr/text/45/46.116) and identifiable biospecimens. Waiver or alteration of consent in [research](https://www.law.cornell.edu/cfr/text/45/46.116) involving public benefit and service programs conducted by or subject to the approval of [state](https://www.law.cornell.edu/cfr/text/45/46.116) or local officials is described in [paragraph (e)](https://www.law.cornell.edu/cfr/text/45/46.116#e) of this section. General waiver or alteration of informed consent is described in [paragraph (f)](https://www.law.cornell.edu/cfr/text/45/46.116#f) of this section. Except as provided elsewhere in this policy:

**(1)** Before involving a human subject in [research](https://www.law.cornell.edu/cfr/text/45/46.116) covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's [legally authorized representative](https://www.law.cornell.edu/cfr/text/45/46.116).

**(2)** An investigator shall seek informed consent only under circumstances that provide the prospective subject or the [legally authorized representative](https://www.law.cornell.edu/cfr/text/45/46.116) sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

**(3)** The information that is given to the subject or the [legally authorized representative](https://www.law.cornell.edu/cfr/text/45/46.116) shall be in language understandable to the subject or the [legally authorized representative](https://www.law.cornell.edu/cfr/text/45/46.116).

**(4)** The prospective subject or the [legally authorized representative](https://www.law.cornell.edu/cfr/text/45/46.116) 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.

**(5)** Except for broad consent obtained in accordance with [paragraph (d)](https://www.law.cornell.edu/cfr/text/45/46.116#d) of this section:

**(i)** Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or [legally authorized representative](https://www.law.cornell.edu/cfr/text/45/46.116) in understanding the reasons why one might or might not want to participate in the [research](https://www.law.cornell.edu/cfr/text/45/46.116). This part of the informed consent must be organized and presented in a way that facilitates comprehension.

**(ii)** Informed consent as a whole must present information in sufficient detail relating to the [research](https://www.law.cornell.edu/cfr/text/45/46.116), 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 [legally authorized representative](https://www.law.cornell.edu/cfr/text/45/46.116)'s understanding of the reasons why one might or might not want to participate.

**(6)** No informed consent may include any exculpatory language through which the subject or the [legally authorized representative](https://www.law.cornell.edu/cfr/text/45/46.116) 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](https://www.law.cornell.edu/cfr/text/45/46.116), or its agents from liability for negligence.

**(b)*Basic elements of informed consent.*** Except as provided in paragraph (d), (e), or (f) of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

**(1)** A statement that the study involves [research](https://www.law.cornell.edu/cfr/text/45/46.116), an explanation of the purposes of the [research](https://www.law.cornell.edu/cfr/text/45/46.116) and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

**(2)** A description of any reasonably foreseeable risks or discomforts to the subject;

**(3)** A description of any benefits to the subject or to others that may reasonably be expected from the [research](https://www.law.cornell.edu/cfr/text/45/46.116);

**(4)** A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

**(5)** A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

**(6)** For [research](https://www.law.cornell.edu/cfr/text/45/46.116) involving more than [minimal risk](https://www.law.cornell.edu/cfr/text/45/46.116), an explanation as to whether any compensation and an explanation as to whether any medical treatments 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](https://www.law.cornell.edu/cfr/text/45/46.116) and [research](https://www.law.cornell.edu/cfr/text/45/46.116) subjects' rights, and whom to contact in the event of a [research](https://www.law.cornell.edu/cfr/text/45/46.116)-related injury to the subject;

**(8)** A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and

**(9)** One of the following statements about any [research](https://www.law.cornell.edu/cfr/text/45/46.116) that involves the collection of [identifiable private information](https://www.law.cornell.edu/cfr/text/45/46.116) or identifiable biospecimens:

**(i)** A statement that identifiers might be removed from the [identifiable private information](https://www.law.cornell.edu/cfr/text/45/46.116) or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future [research](https://www.law.cornell.edu/cfr/text/45/46.116) studies or distributed to another investigator for future [research](https://www.law.cornell.edu/cfr/text/45/46.116) studies without additional informed consent from the subject or the [legally authorized representative](https://www.law.cornell.edu/cfr/text/45/46.116), if this might be a possibility; or

**(ii)** A statement that the subject's information or biospecimens collected as part of the [research](https://www.law.cornell.edu/cfr/text/45/46.116), even if identifiers are removed, will not be used or distributed for future [research](https://www.law.cornell.edu/cfr/text/45/46.116) studies.