Human Subject Consent for Research

General requirements for informed consent.

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.

1. Investigator shall seek informed consent only under circumstances that:
   1. that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate
   2. minimize the possibility of coercion or undue influence.
2. Information given to the subject or the legally authorized representative shall be in understandable language
3. The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would need to make an informed decision about participation, and an opportunity to discuss that information.

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 in understanding the reasons why

Basic elements of informed consent include:

1. A statement that the study involves research, including an explanation of the purposes of the research
2. The expected duration of the subject’s participation
3. A description of the procedures to be followed, and identification of any procedures that are experimental
4. A description of any reasonably foreseeable risks or discomforts to the subject
5. A description of any benefits to the subject or to others that may reasonably be expected from the research
6. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
7. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
8. For research involving more than minimal risk
   1. explanation as to whether any compensation
   2. 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
9. An explanation of whom to contact for answers to pertinent questions about the research, research subjects’ rights, and in the event of a research-related injury
10. A statement that participation is voluntary, including:
    1. refusal to participate will involve no penalty or loss of benefits
    2. the subject may discontinue participation at any time without penalty
11. One of the following statements about research involving the collection of identifiable private information or identifiable biospecimens:
12. identifiers might be removed from private information/biospecimens. After removal, the information/biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional information
13. information/biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Additional elements of informed consent, when appropriate, include:

* 1. A 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) that are currently unforeseeable
  2. Anticipated circumstances under which the subject’s participation may be terminated by the investigator
  3. Additional costs to the subject resulting from participation in the research;
  4. Consequences of a subject’s decision to withdraw from the research
  5. Procedures for orderly termination of participation by a subject
  6. A statement that significant new findings during the research that may relate to a subject’s willingness to continued participation will be provided to the subject
  7. The approximate number of subjects involved in the study
  8. A statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and if the subject will/will not share in the profit
  9. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions
  10. For research involving biospecimens, whether the research will or might include whole genome sequencing.

Elements of broad consent

Broad consent for the storage, maintenance, and secondary research use of identifiable private information/ biospecimens (collected for either research studies other than the proposed research or non-research purposes) is permitted as an alternative to informed consent.

Broad consent information requirement provided to each subject or the subject’s legally authorized representative include:

1. A general description of the types of research that may be conducted with the identifiable private information/identifiable biospecimens. The description must include information that a reasonable person would need to make an informed decision about participation, and an opportunity to discuss that information.
2. A description of the identifiable private information/identifiable biospecimens that might be used in research, whether the identifiable private information/identifiable biospecimens might be shared, and the types of institutions/researchers that might conduct the research
3. A description of the period of time that the identifiable private information/identifiable biospecimens may be stored and maintained, and a description of the period of time that the identifiable private information/identifiable biospecimens may be used for research purposes (could be indefinite) time period)
4. A statement that subjects will not be informed of the details of any specific research studies using their identifiable private information/identifiable biospecimens (Unless subjects will be provided details). This includes research purposes, and that they might have chosen not to consent to the research studies.
5. A statement that such research results may not be disclosed to subjects (unless results will be disclosed to subject in all circumstances)
6. An explanation of whom to contact for answers to questions and in the event of research-related harm

General waiver or alteration of consent.

An IRB may waive the requirement to obtain informed consent for research or approve a consent procedure that omits some, or alters some or all, of the elements of informed consent. If an individual refused broad consent for the storage, maintenance, and secondary research use of identifiable private information/identifiable biospecimens, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the individual’s identifiable private information or identifiable biospecimens. In order for an IRB to waive or alter consent, the IRB must find and document that:

1. The research involves no more than minimal risk to the subjects;
2. The research could not practicably be carried out without the requested waiver or alteration;
3. The research involves using identifiable private information/identifiable biospecimens and could not practicably be carried out without using them in an identifiable format
4. The waiver or alteration will not adversely affect the rights and welfare of the subjects
5. When appropriate, subjects or legally authorized representatives will be provided additional pertinent information after participation.

Subpart A of 45 CFR Part 46: Basic HHS Policy for Protection of Human Subjects, §46.116

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