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Written Consent

There are six general requirements for informed consent:

1. Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.
2. An investigator shall seek informed 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.
3. The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.
4. The prospective subject or the legally authorized 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.
5. Except for broad consent obtained
    a. 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 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.
    b. 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 legally authorized representative'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 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.

There are nine required basic elements of consent that must be included in a consent document:

1. statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject'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 subject;
3. A description of any benefits to the subject 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 subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

6. For research involving more than minimal risk, 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 and research subjects' rights, and whom to contact in the event of a research-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;
9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
    a. A statement that the 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 subject or the legally authorized representative, if this might be a possibility; or
    b. A 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.

The Federal regulations also include nine additional elements that may be included when appropriate:

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 without regard to the subject's or the legally authorized representative's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
6. The approximate number of subjects involved in the study;
7. A 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 this commercial profit;
8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, 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).

Waiver of Consent Documentation

Under Federal regulations, a waiver of documentation of consent may be granted by the IRB when it is appropriate to the type of research or the research methods. A waiver of documentation of consent is not a waiver of the consent process-- it is a waiver of the requirements to obtain a signature from the subject.

Examples:

- Telephone interviews
- Online surveys
- Research where the only documentation connecting participants and the project is a signed consent form

Consent documentation can be waived if any of the following are true:

1. The only record linking the subject and the research would be the informed consent form, and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; **or**
2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; **or**
3. If the subjects are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained

Waiver or Alteration of Consent

This section discusses the most relevant requirements, see 45 CFR 46.116 for the complete requirements on informed consent, including waivers and alterations.

Waiver: When the consent process is waived in its entirety, all elements of the consent process are waived, so there is no form or information provided to the subject, and no verbal discussion of the research with the subject before they are enrolled or become subjects in the research. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements under the elements of broad consent, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens

Alteration: An alteration of informed consent involves a change in or omission of one or more of the required elements of consent. An IRB may not omit or alter any of the requirements described in the general requirements of informed consent. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under the elements of broad consent.

- **For research examining state or local public benefit or service programs (45 CFR 46.116(c)):** Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials is possible if the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
  a) Public benefit or service programs;
  b) Procedures for obtaining benefits or services under those programs;
  c) Possible changes in or alternatives to those programs or procedures; **or**
  d) Possible changes in methods or levels of payment for benefits or services under those programs; **and**
  e) The research could not practicably be carried out without the waiver or alteration.

- **For general waiver or alteration of consent (45 CFR 46.116(f)):** In order for the IRB to waiver 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. If the research involves using identifiable private information, the research could not practicably be carried out without using such information;
  4. The waiver or alteration will not adversely affect the rights and welfare of the subjects; **and**
  5. When appropriate, subjects will be provided with pertinent information after their participation

- **For screening, recruiting, or determining eligibility (45 CFR 46.116(g)):** Under an IRB may approve a research proposal in which investigators obtain information for the

purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subjects if either are met:

a) Investigators will obtain information through oral or written communication with the prospective subject; **or**
b) The investigator will obtain identifiable private information by accessing records

Broad Consent

Broad consent is required under exemption categories 7 or 8. Broad consent is a new type of informed consent provided under the Federal regulations for human subject research that involves the storage, maintenance, and secondary research of identifiable private information. Broad consent does not apply to research that collects information from individuals through direct interaction or intervention specifically for the purpose of research.

Informed consent requirements applicable to broad consent:

- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others that may reasonably be expected from the research;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; and
- 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 (if applicable)
- A 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 this commercial profit;
- For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing

Additional broad consent requirements:

- A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;
- A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;
- A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);
- Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;
- Unless it is known that clinically relevant research results, including individual research

results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; **and**

- An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.