

**Informed consent process**

- Informed consent may start with study recruitment; however, in accordance with §46.116(g), researchers may obtain private, identifiable information for screening, recruiting, or eligibility purposes without informed consent if the researcher obtains that information through:
  1. Oral or written communication with the potential research subject; or
  2. Accessing records
- Consent must be legally effective (i.e., consent from person who has authority to consent)
- Research subjects must receive specific information about the study in a way that is understandable (e.g., appropriate reading level or language other than English) to them
- Research subjects should be encouraged to ask questions about their participation and the research study
- Informed consent must be obtained under circumstances that allow the research subject sufficient time to decide whether or not to participate
- Informed consent must be obtained without undue influence or pressure, and free from a retaliatory response from those with authority over a research subject
- Researchers should monitor a research subject's continued willingness to participate as a study progresses.

**Basic required elements of informed consent that should be in a consent form (unless one or more of the elements are waived by the IRB)**

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of each procedure and entire duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
3. 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
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 which may reasonably be expected from the research;
6. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
7. For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained;
8. Applicable to identifiable data, research subjects must be provided with:
  - i. A statement that identifiers might (or will) be removed from the identifiable private information (or identifiable bio-specimens); **AND**

- ii. The information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent **OR** a statement that the research subject's information collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.
9. An explanation of whom to contact for answers about the research study and whom to contact for questions about research subjects' rights.

**Additional elements for informed consent (may be a requirement), when appropriate**

When applicable, one or more of the following elements shall be in the consent form:

1. The approximate number of research subjects involved in the study;
2. An option for the research subject to agree to be re-contacted by the researchers to collect additional research data or to discuss participation in a future research study;
3. A statement whether clinically relevant research results, including individual results, will be disclosed to research subjects, and if so, under what conditions;
4. A statement that significant new findings developed during the course of the research, which may relate to the research subject's willingness to continue participation, will be provided to the research subject;
5. A statement that the particular treatment or procedure may involve risks to the research subject (or embryo/fetus, if subject is or may become pregnant), which are currently unforeseeable;
6. The consequences, particularly in clinical therapies, of a research subject's decision to withdraw from the research and procedures for termination of participation by the research subject;
7. Any additional costs to the subject that may result from participation in the research;
8. A statement that the research subject's bio-specimens may be used for commercial profit and whether the research subject will or will not share in this commercial profit;
9. A statement whether bio-specimens might be used for whole genome sequencing;
10. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the research subject's consent.

The IRB may require that additional information beyond the basic and additional elements be included in the consent form, when in the IRB's judgment the additional information would meaningfully add to key information or the protection of research subjects' rights.

**Typical types of consent:** Written consent is in the form of a written signature, an electronic signature, an uploaded scanned document carrying a signature (Note: a simple printed name or checkbox click could be documentation of consent if the research subjects have to login with a personal identification). Oral consent is verbal agreement to be a research participant. A consent form that states that by responding to online questions or clicking a checkbox is generally an alteration of signed consent, which the IRB may approve as implied consent and as an alteration of the consent process.