

Informed consent process

- Private, identifiable information for screening, recruiting, or eligibility purposes without informed consent may be conducted but only if the information is obtained through:
 1. Oral or written communication with the potential research subject; or
 2. Having permissible access to private records for research purposes
- Legal consent is obtained from individuals who have reached the age of majority, or are legally emancipated youth, or who are legally authorized representatives
- Informed consent starts with study recruitment by providing potential research participants with adequate information (e.g., research title or research topic, investigators' name/institution, inclusion criteria to be eligible, and brief description of study participation, including time commitment)
- Consent scripts must begin with key information and be understandable (e.g., appropriate reading level or language other than English) to the study population(s)
- Consent must be obtained under circumstances that allow the research subject sufficient time to ask questions and decide whether or not to participate
- Consent must be obtained without undue influence or pressure, and be 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
- Consent scripts must include the required basic elements of consent (and additional elements if applicable) unless the IRB waives some or all of the elements

Required elements for informed consent forms (non-exempt research):

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 participation, including follow-ups, 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 research subjects;
3. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the research subjects are otherwise entitled, and that the research subjects may discontinue participation at any time without penalty or loss of benefits, to which they are otherwise entitled
4. A description of any reasonably foreseeable research risks to research subjects;
5. A description of any direct benefits to research subjects or to society which may reasonably be expected from the research;
6. A statement describing the extent to which confidentiality of records identifying research subjects will be maintained;
7. 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 may 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 subjects' information collected as part of the research, even if identifiers are removed, will not be used or distributed for future research;
8. An explanation of whom to contact (investigator) for answers about the research study and whom to contact (IRB) for questions about research subjects' rights;
 9. When applicable, 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.

Additional elements for informed consent forms, when applicable (non-exempt research):

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 for 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 research 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;
7. Any additional costs to the research 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 research subject's participation may be terminated by the investigator without regard to the research subject's consent.

NOTE: 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 research subjects' rights.

Typical types of consent: 1) Written consent is in the form of a written signature, an electronic signature, an uploaded scanned document carrying a signature. A printed name or checkbox click could be documentation of consent if the research subjects have to login with a personal identification and/or documentation is traceable to the research subject; 2) Oral consent is verbal agreement; and 3) Implied consent is an alteration of consent. For example, if a research subject completes an online survey without checking a traceable link or checkbox.

Required 12 elements for broad consent forms (exempt research only):

1. A description of the types of future or secondary research that may occur with the identifiable private information. The scope of the broad consent must include enough information to permit a reasonable person to understand the scope of future research that may be conducted;
2. A description of the private information that might be used in future or secondary research; whether sharing might occur; and the types of institutions or researchers that might conduct research using the private information;
3. A description of any reasonably foreseeable risks or discomforts to the data subjects;
4. A description of any benefits to the subject or to others that may reasonably be expected;
5. Unless the data subject or subject's 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 future research studies that might be conducted using the data subject's private information, including details of the research and that they might have chosen not to consent to some future research purposes;
6. A statement describing the extent to which confidentiality of records identifying the subject will be maintained;
7. A description of the length of time that the private information may be stored, maintained, and used for research purposes;
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the data subject is otherwise entitled, and the data subject may discontinue participation, withdraw their data, at any time without penalty or loss of benefits to which the subject is otherwise entitled;
9. 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 research results will not be disclosed to the data subject;
10. An explanation of whom to contact regarding questions about data storage and use of the data subject's private information (principal investigator), and whom to contact in the event of a research-related harm (IRB);
11. A statement that data subjects' bio-specimens (even if identifiers are removed) may be used for commercial profit and whether the data subjects will or will not share in this commercial profit; and
12. A statement on whether the research will 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).