Regulatory Requirements for Informed Consent

Federal regulations state that informed consent given to research participants must include basic information and may also contain additional elements if they apply. Check consent materials to make sure they include all required elements and any applicable additional elements.

Some studies may be subject to further requirements due to the nature of the research (e.g., use of FERPA-regulated information), sponsor requirements, etc.

Basic Elements of Informed Consent • All of the basic elements of consent listed below (except for #6) must be in all consent forms unless a waiver for one or more of these elements has been approved by the IRB. • Bolded elements were newly added in the 2018 revised Common Rule.	
Invitation to Participate, Purpose of Research, Time Spent, and Procedures	1. Statement that study involves research, Explanation of the purposes of the research and the expected duration of the subjects' participation, A description of the procedures to be followed, and Identification of any procedures that are experimental;
Risks	2. Description of any reasonably foreseeable risks or discomforts to the subject;
Benefits	3. Description of any benefits to the subject or to others that may reasonably be expected from the research;
Alternatives	4. Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
Privacy & Confidentiality	5. Statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
Injury-related* Compensation	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; ** Injury means any research-related injury (i.e., physical, psychological, social, financial, or otherwise). The regulations do not limit injury to "physical injury".* **Informed Consent Tips** (OPRR 1993)
Contact Information	7. 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;
Participant Rights	8. 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;
Future Research	9. **Statement that 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 LAR, if this might be a possibility,** **- OR -** **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.**

Additional Elements of Informed Consent

- The elements below are required when applicable to the research study
- Bolded elements were newly added in the 2018 revised Common Rule.

Pregnancy	1. 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) which are currently unforeseeable;
Discontinuation for Research	2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
Costs	3. Any additional costs to the subject that may result from participation in the research;
Consequences of Withdrawal	4. Consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
New Findings	5. Statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject;
Number of Participants	6. Approximate number of subjects involved in the study;
Commercial Profit	7. **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;**
Clinically Relevant Results	8. **Statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and**
Whole Genome Sequencing	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).**

Resources

HHS Regulations and Guidance

- Regulations 45 CFR 46.116, Federal Register Volume 82, Number 12 (January 19, 2017), pp. **7265 – 7267**
- OHRP **Informed Consent FAQ**
- OHRP **Guidance Documents on Informed Consent**

FDA Regulations and Guidance

The new elements of informed consent introduced in the 2018 revised Common Rule are not included in the elements of informed consent required by the FDA.

- General Requirements for Informed Consent: **21 CFR 50.20**
- Elements of Informed Consent: **21 CFR 50.25**
- FDA **Guide to Informed Consent Information Sheet**