Basic and Additional Elements of Consent

Regulations require that the informed consent document must include certain basic information and additional optional elements if applicable. When writing the informed consent document, investigators should ensure that each required element is included. Additional elements are to be included when they provide additional information of value to the reader.

The elements of consent are outlined in the Common Rule. All of the basic elements (outlined below) must be in all consent forms, and the additional elements may be used as applicable.

Basic Elements of Consent

Invitation to Participate, Purpose of Research, and Procedures	(1) A 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
Risks	(2) A description of any reasonable foreseeable risks or discomforts to the subject
Benefits	(3) A description of any benefits to the subject or to others which may reasonably be expected from the research
Alternatives	(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
Privacy & Confidentiality	(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
Injury 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
Contact Information	(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
Subject Rights	(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 subjects is otherwise entitled
Research Involving Identifiable Biospecimens	(9) (a) A 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 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

Additional Elements of Consent

Pregnancy	(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) which are currently unforeseeable
Discontinuation from 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) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
New Findings	(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
Number of Participants	(6) The 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 Research Results	(8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions
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)