General Requirements for Informed Consent	Citation (45 CFR)
o Obtain informed consent from the subject or the subject's legally authorized representative before involving the subject in human subjects research.	_.116(a)(1)
o Obtain informed consent under circumstances that provide the prospective subject or subject's legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.	_.116 (a)(2)
o Information must be in a language understandable to the subject or the legally authorized representative.	_.116(a)(3)
o **Prospective subject or subject's 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 the information.**	**_.116(a)(4)**
o **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. This part of the consent must be organized and presented in a way that facilitates comprehension.** o **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.**	**_.116(a)(5)**
o 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, or the institution from liability for negligence.	_.116(a)(6)
Basic Elements of Informed Consent (bold identifies new elements in the 2018 Rule)	**Citation (45 CFR)**
o Statement that study involves research, o Explanation of the purposes of the research and the expected duration of the subjects' participation, o A description of the procedures to be followed, and o Identification of any procedures that are experimental	_.116(b)(1)
o Description of any reasonably foreseeable risks or discomforts to the subject	_.116(b)(2)
o Description of any benefits to the subject or to others that may reasonably be expected from the research	_.116(b)(3)
o Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject	_.116(b)(4)
o Statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained	_.116(b)(5)
o 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	_.116(b)(6)
o 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	_.116(b)(7)
o 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	_.116(b)(8)
o **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 -** o **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**	**_.116(b)(9) (i) and (ii)**

	Additional Elements of Informed Consent (as appropriate to the research) (bold identifies new elements in the 2018 Rule)	Citation (45 CFR)
o	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	_.116(c)(1)
o	Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent	_.116(c)(2)
o	Any additional costs to the subject that may result from participation in the research	_.116(c)(3)
o	Consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject	_.116(c)(4)
o	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	_.116(c)(5)
o	Approximate number of subjects involved in the study	_.116(c)(6)
o	**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**	**_.116(c)(7)**
o	**Statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and**	**_.116(c)(8)**
o	**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)**	**_.116(c)(9)**

Adapted from original University of Michigan document.