2019 Common Rule: Review of Required and Additional Elements and Other Required Provisions

A. Verify that the informed consent process addresses each of the general requirements (45 CFR 46.116a)

Yes	No	Item #	ITEMS
			GENERAL REQUIREMENTS
		1	Consents/assents for all subjects or subject/s LAR except those for whom consent is waived
		2	Consent will be obtained under circumstances that minimize the possibility of coercion or undue influence
		3	Consent will be given in a language understandable to the subject or LAR
		4	Consent includes information that a reasonable person would want to have in order to make an informed decision
		5i	Consent begins with a concise and focused presentation of the information that is most likely to assist a subject in understanding why s/he might or might not want to participate
		5ii	Consent must be organized and presented in a way that does not merely provide lists of isolated facts.
		6	Consent does not include exculpatory language through which the subject is made to waive legal rights.

B. Verify that the informed consent document contains each of the basic elements of informed consent (45 CFR 46.116b)

Yes	No	Item #	ITEMS
			REQUIRED ELEMENTS
		1a	a statement that the study involves research, and
		1b	an explanation of the purposes of the research, and
		1c	the expected duration of the participant ‘s participation, and
		1d	a description of the procedures to be followed, and
		1e	identification of any procedures which are experimental;
		2	a description of any reasonably foreseeable risks or discomforts to the participant;
		3	a description of any benefits to the participant or to others which may reasonably be expected from the research
		4	a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;
		5a	a statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained; and
		5b	if applicable, includes a statement about the possibility that external regulatory agencies, may inspect the records
		6a	for research involving more than minimal risk, an explanation as to whether any compensation is available if injury occurs, and
		6b	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;
		7a	an explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and
		7b	whom to contact in the event of a research-related injury to the participant;
		8a	a statement that participation is voluntary, and
		8b	a statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and
		8c	a statement that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

Yes	No	Item #	ITEMS
		9	One of the following statements about research that involves the collection of identifiable private information or identifiable biospecimens: i. A statement that identifiers might be removed from the information or biospecimens and that, after such removal, the information or specimens could be used for future research studies or distributed to another investigator for future studies without additional informed consent being obtained. ii. A statement that the information or biospecimens, even if identifiers are removed, will not be used or distributed for future research studies.

C. Verify that where appropriate, one or more of the following additional elements of information is provided in the consent form (45CFR46.116c).

Yes	NA	Item #	ITEMS
	ADDITIONAL ELEMENTS		
		1a	a statement that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable; and
		1b	if the participant is or may become pregnant, a statement that the particular treatment or procedure may involve risks to the embryo or fetus which are currently unforeseeable;
		2	anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent;
		3	any additional costs to the participant that may result from participation in the research;
		4a	the consequences of a participant's decision to withdraw from the research; and
		4b	the procedures for orderly termination of participation by the participant;
		5	a statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant
		6	the approximate number of participants involved in the study.
		7a	a statement that the subject's biospecimens may be used for commercial profit
		7b	a statement about whether the subject will or will not share in the commercial profit
		8	a statement about whether clinically relevant results, including individual results will be disclosed to the participant and if so, under what conditions
		9	A statement about whether the research will, or might (if known), include whole genome sequencing

D. In addition to the required elements, the following must be included, if applicable:

Yes	NA	Other Mandatory Consent Provisions, if applicable
		A statement about Individual or Institutional Conflict of Interest
		If this is a clinical trial, a statement that the research will be entered into the clinical trials.gov website.
		Genomic Data Sharing Policy language
		Certificate of Confidentiality language for NIH funded studies