Present (or N/A)	Required Elements of Consent
	For lengthy and/or complex consent documents, a concise and focused summary of the key information
	A statement that participation is voluntary
	A statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled
	A statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled
	A statement that the study involves research
	An explanation of the purposes of the research
	Identification of any procedures that are experimental
	A description of the procedures to be followed
	The expected duration of the subject's participation
	A description of any reasonably foreseeable risks or discomforts to the subject
	A description of any benefits to the subject or to others that may reasonably be expected from the research
	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
	For FDA-regulated research, a statement that informs the subject of the possibility that FDA may inspect the records
	For FDA-regulated research involving an applicable clinical trial, a statement notifying the subject that clinical trial information that has been or will be submitted for inclusion in ClinicalTrials.gov
	For research involving the collection of identifiable information or biospecimens, a statement that identifiers might be removed and used for future research studies or distributed to another investigator for future research without additional informed consent, or a statement that the subject's information/biospecimens will not be used or distributed for future research studies even if identifiers are removed
	For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available if injury occurs, and, if so, what they consist of or where further information may be obtained
	An explanation of whom to contact for answers to pertinent questions about the research

	An explanation of whom to contact for answers to pertinent questions about the research subjects' rights
	An explanation of whom to contact in the event of a research-related injury or harm to the subject
Present (or N/A)	**Additional Elements of Consent (if applicable to the research)**
	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) that are currently unforeseeable
	Anticipated circumstances under which participation may be terminated by the investigator without the subject's consent
	Any additional costs to the subject that may result from research participation
	Consequences of a subject's decision to withdraw from the research and procedures for orderly termination of the subject's participation
	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
	Approximate number of subjects involved in the study
	A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether or not the subject will share in this commercial profit
	A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions
	For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing