Required Elements of Informed Consent:

A. Begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject in understanding the reasons why might or might not want to participate in research.
B. A statement that the study involves research
C. An explanation of the purposes of the research
D. The expected duration of the subject's participation
E. A description of the procedures to be followed
F. Identification of any procedures which are experimental
G. A description of any reasonably foreseeable risks or discomforts
H. A description of any benefits to the subject, or others, which may reasonably be expected from the research
I. Disclosure of appropriate alternative procedures or treatments, if any, that might be advantageous to the subject
J. Description of extent, if any, to which confidentiality of records identifying the subject will be maintained
K. Information on who to contact in the event of a research related injury
L. Information on who to contact for answers to questions about the research
M. Information on who to contact for answers to questions about the research subjects' rights
N. A statement that participation is voluntary and that refusal to participate will result in no penalty and no loss of benefits to which the subject is otherwise entitled
O. A statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled
P. A statement that identifiers might be removed from identifiable private information or identifiable biospecimens and that the information or biospecimens might be used in future research, if that's a possibility OR a statement that information or biospecimens collected for the study will not be used for future research, even if identifiers are removed.
Q.For research involving greater than minimal risk, an explanation as to whether there is any compensation available if injury occurs and, if so, what it consists of or where further information may be obtained
R. For research involving greater than minimal risk, an explanation as to whether there are any medical treatments available if injury occurs and, if so, what they consist of or where further information may be obtained

Additional elements of informed consent that must be included when appropriate to the circumstances of the research:

S. A statement that the particular treatment or procedure may involve risks to the subject (or to the fetus or embryo if the subject is or may become pregnant) which are currently unforeseeable
T. Anticipated circumstances in which the subject's participation may be terminated by the investigator without regard to the subject's consent
U. Any consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
V. Any additional costs to the subject that may result from participation in the research
W. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation in the study will be provided to the subject
X. The approximate number of subjects involved in the study
Y. A statement whether identifiable private information or identifiable biospecimens will be used for future studies
Z. If appropriate, information on whether biospecimens will be used for commercial profit and, if so, whether the subject will benefit from that profit.
AA. If appropriate, a statement whether results will be disclosed to the subject
BB. If appropriate, a statement whether the research might include whole genome sequencing