Required Elements of Informed Consent

- A statement that the study involves research, explanation of the purposes of the research, expected duration of participation, description of the procedures to be followed, and identification of any procedures that are experimental
- 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
- 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
- Explanation of whom to contact for answers to pertinent questions about the research and the subject’s rights and whom to contact in the event of a research-related injury to the subject
- 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 that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- One of the following statements about any research that involves the collection of identifiable private information or identifiable bio-specimens:
  - A statement that identifiers might be removed from the identifiable private information or identifiable bio-specimens and that, after such removal, the information or bio-specimens 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
  - A statement that the subject’s information or bio-specimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.
- For research involving greater than minimal risk, an explanation about whether:
  - Medical treatments are available if injury occurs and, if so, what they consist of or where further information can be obtained
  - Compensation is available if injury occurs and, if so, an explanation as to what it consists of or where further information can be obtained.
- For research regulated by FDA:
  - A statement that informs the subject of the possibility that FDA may inspect the records
  - For applicable clinical trials, the following statement notifying the subject that clinical trial information has been or will be submitted for inclusion in the clinical trial registry databank: “A description of this clinical trial will
be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."

**Additional Elements of Informed Consent**

- 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 regard to the subject’s consent
- Any additional costs to the subject that may result from participation in the research
- Consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject
- 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 bio-specimens (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 bio-specimens, whether the research will (if known) or might include whole genome sequencing.