Informed Consent Process

- Begins with recruitment and screening of a research subject including advertisements and discussions that occur during the screening process
- Provide specific information about the study in a way that is understandable to potential research subjects while giving them adequate time to consider participation
- Answering the potential research subject’s questions
- Obtaining the voluntary agreement of the research subject to take part in the study
- Verifying the research subject’s continued consent to participate as the study progresses.

Informed Consent Checklist - Required Basic Elements of Consent (Revised Common Rule)

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of each procedure and entire duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
3. 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 the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled
4. A description of any reasonably foreseeable risks or discomforts to the subject;
5. A description of any benefits to the subject or to others which may reasonably be expected from the research;
6. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
7. For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained;
8. For research involving collection of identifiable private information or identifiable biospecimens, subjects must be provided with:
   i. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens; and
   ii. The information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent, where applicable OR a 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.
9. An 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 harm to the subject.
Additional Required Elements of Consent When Applicable

When appropriate or applicable, one or more of the following elements of information shall also be provided to each subject:

1. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions;
2. A statement that the subject’s bio-specimens may be used for commercial profit and whether the subject will or will not share in this commercial profit;
3. A statement whether biospecimens might be used for whole genome sequencing;
4. The approximate number of subjects involved in the study;
5. An option for the subject or the representative to consent, or refuse to consent, to investigators re-contacting the subject to seek additional information or to discuss participation in another research study;
6. A 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;
7. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
8. Any additional costs to the subject that may result from participation in the research;
9. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject; or
10. 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), which are currently unforeseeable.

General IRB Requirements

- Consent must be legally effective (i.e., consent from person who has authority to consent)
- The language used (written and oral) to obtain consent must be understandable to the research subject or the research subjects’ Legally Authorized Representative (LAR)
- Consent must be obtained under circumstances that allow the subject or LAR sufficient time to decide whether or not to participate
- Consent must be obtained without undue influence or coercion and free from a retaliatory response from senior members of a hierarchy (e.g., head of a household) in cases of refusal to participate.

General Types of Consent

Explicit consent is in the form of a written signature, an electronic signature, an uploaded scanned document carrying a signature; Oral consent is verbal agreement to be a participant; or Implicit consent is in the form of online surveys or text where participants verify consent by clicking on a verification link or check a box prior to a second step of providing information.