**Informed Consent**

**General Requirements for Informed Consent:**

* The investigator shall obtain the legally effective informed consent of the prospective participant or the participant’s legally authorized representative.
* The investigator shall seek informed consent only under circumstances that provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.
* The information that is given to the participant or the legally authorized representative shall be in language understandable to the participant or the legally authorized representative.
* The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
* Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
* Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject’s or legally authorized representative’s understanding of the reasons why one might or might not want to participate.
* The informed consent does not include any exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant’s legal rights releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

**Informed Consent**

**Information that must be provided as part of the interaction with the participant *and* in the documentation of the consent process, unless waived or altered:**

* A statement that the study involves research.
* An explanation of the purposes of the research.
* The expected duration of the participant’s participation.
* A description of the procedures to be followed.
* Identification of any procedures which are experimental.
* A description of any reasonably foreseeable risks or discomforts to the participant.
* A description of any benefits to the participant or to others which 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 participant.
* A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained
* 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 participant’s rights.
* An explanation of whom to contact in the event of a research-related injury to the participant.
* Contact information for the research team for questions, concerns, or complaints.
* Contact information for someone independent of the research team for problems, concerns, questions, information or input.
* A statement that participation is voluntary.
* A statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled.
* A statement that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
* One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
  + A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens 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 biospecimens collected as part of the research, even if identifiersare removed, will not be used or distributed for future research studies.
* ***For research involving more than minimal risk:***
  + An explanation as to whether any compensation is available if injury occurs.
  + If compensation is available, what it consists of, or where further information may be obtained.
  + An explanation as to whether any medical treatments are available if injury occurs.
  + If medical treatments are available if injury occurs, what it consists of, or where further information may be obtained.
* ***For FDA-regulated Research:***
  + A statement that notes the possibility that the Food and Drug Administration may inspect the records.

**Additional Elements of Informed Consent:**

One or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

* 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 the subject’s participation may be terminated by the investigator without regard to the subject’s or the legally authorized representative’s consent;
* (Any additional costs to the subject that may result from participation in the research;
* (The 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 to the subject;
* The 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 the subject will or will not 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; and
* For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).
* For applicable clinical trials, a statement notifying the clinical trial subject that clinical trial information has been or will be submitted for inclusion in the clinical trial registry databank. The statement is: “A description of this clinical trial will be available on http://ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.”

**Criteria for Approval of Research**

In order to approve research the IRB shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized.

* Procedures are consistent with sound research design and do not unnecessarily expose subjects to risk.
* Study utilizes procedures already performed for diagnosis/treatment -- when appropriate.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result.

3. Selection of subjects is equitable.

* Inclusion/exclusion criteria are adequate.
* Research purpose and setting are appropriate.
* Recruitment process is fair.
* Special requirements for vulnerable populations are addressed.

4. Informed consent will be sought or waived in accordance with 45 CFR 46.116— and 21 CFR 50.25 for FDA-regulated research.

5. Informed consent will be documented or documentation waived in accordance with 45 CFR 46.117—and 21 CFR 50.27 for FDA-regulated research

6. Provisions for monitoring collected data are adequate to ensure the safety of subjects -when appropriate.

7. Provisions to protect privacy of subjects are adequate – when appropriate. Provisions to maintain confidentiality of data are adequate – when appropriate.

8. Vulnerable populations are adequately protected by additional safeguards.

* Children
* Prisoner
* Pregnant women, fetuses and neonates
* Cognitively impaired persons
* Economically and educationally disadvantaged persons
* Non-English speaking persons

9. If multi-site research study management of information relevant to protection of subjects is adequate.

**Additional Considerations:**

* ***For Initial Review:***
  + Should review be obtained more often than annually?
  + If this is a multi-site research study, is the management of information that might be relevant to the protection of participants adequate?
* ***For Continuing Review:***
  + Should review be obtained more often than annually?
  + Should verification be obtained from sources other than the investigator that no material changes have taken place since prior IRB review?
  + Is the consent document accurate and complete?
  + If information has arisen that might affect the willingness of participants to continue to take part in the research, will it be provided to those participants?
* ***For Review of Modifications to Previously Approved Research:***
  + If information has arisen that might affect the willingness of participants to continue to take part in the research, will it be provided to those participants?

**Belmont Report**

The unifying ethical principles that form the basis for the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research:

* **respect** for persons: protecting the autonomy of all people and treating them with courtesy and respect and allowing for informed consent;
* **beneficence**: maximizing benefits for the research project while minimizing risks to the research subjects; and
* **justice**: ensuring reasonable, non-exploitative and well-considered procedures are administered fairly (the fair distribution of costs and benefits.)