## BACKGROUND
Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied. The common rule establishes standard for informed consent.

## SCOPE
The purpose of this policy is to provide a description the required elements of informed consent and the review process for the IRB.

## AUTHORITY
45 CFR 46.116(a) & 21 CFR 50.25(a) Requirements for consent
45 CFR 46.116(b) & 21 CFR 50.25(b) Additional requirements for consent

### I. POLICY

**A.** Legally effective informed consent requires that the basic elements of informed consent 45 CFR 116, and additional elements when appropriate, are included in the consent form, unless a waiver or alteration is approved by the IRB. (Amendment A)

**B.** No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

**C.** The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.

**D.** The consent form should only have language that minimizes the possibility of coercion or undue influence.

**E.** The document should have appropriate spaces to document legally effective informed consent of the subject or the subject's legally authorized representative as required by the IRB and the law.

### II. PROCEDURES

**A.** The PI Submits the Consent form(s) to IRB for Review

1. The IRB submission should include all proposed consent and assent forms.
2. The documents should be developed using the consent form creation policy and the appropriate template forms [LINK TO FORMS] and appropriate liability language.
3. The consent form(s) should include all of the required elements of informed consent and any relevant additional elements, unless an alteration is requested.

**B.** ORIO Analyst review

1. Validates that the informed consent process is described in IRB applications.
2. Validates that the required elements of informed consent are included in the consent documents submitted.

**C.** IRB review

1. The full board IRB or the expedited reviewer reviews each consent form and requests for waiver or alteration of consent or waiver of the requirement to document consent.
2. The IRB reviews to ensure that the consent forms is understandable by ensuring that:
   a. technical and scientific terms are adequately explained or that common terms are substituted.
   b. the informed consent document properly translates complex scientific concepts into simple concepts that the typical subject can read and comprehend.
3. The IRB removes statements of unproven claims of effectiveness or certainty of benefit, either explicit or implicit, that may unduly influence potential subjects. Overly optimistic representations are misleading and violate FDA regulations concerning the promotion of investigational drugs [21 CFR 312.7] or investigational devices [21 CFR 812.7(d)] as well as the requirement to minimize the possibility of coercion or undue influence [21 CFR 50.20].
4. The reviewer(s) confirm that all of the required elements of consent are satisfied. (See Amendment A)
5. The reviewer(s) confirm that, when necessary, the additional elements of informed consent are satisfied. (See Amendment B)
6. The IRB requires changes as necessary to approve the consent form(s)
7. Post-review, the research team responds to the IRB requests and makes changes to the consent documents in order to secure approval.
8. The IRB approves the finalized forms and provides a stamp which indicates the approval and expiration date of the form(s).

III. Definitions
A. Informed Consent: An individual’s voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure.
B. Informed Consent Templates: Provide specific guidance on how consent documents should be worded and the order in which the information should be presented.
C. Legally Effective Informed Consent – for research purposes, is consent obtained in compliance with all of the legal requirements for informed consent, including content of the consent process and forms and signatures.
A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

a.) A description of any reasonably foreseeable risks or discomforts to the subject;

b.) A description of any benefits to the subject or to others which may reasonably be expected from the research;

c.) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

d.) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

e.) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

f.) 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 injury to the subject; and

g.) 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.

2.) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

a.) 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;

b.) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

c.) Any additional costs to the subject that may result from participation in the research;

d.) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

e.) 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; and

f.) The approximate number of subjects involved in the study.