APPENDIX C: INFORMED CONSENT (IFC) REQUIREMENTS per 45 CFR 46.116

General requirements (a):

- Prior to involving a human subject in research, obtain the legally effective IFC of the subject or the subject's legally authorized representative (LAR);
- Provide sufficient opportunity for the subject or the LAR to discuss and consider whether or not to participate, minimizing the possibility of coercion or undue influence;
- Provide information in a language understandable to the subject or the LAR;
- Provide information that a reasonable person would want to have in order to make an informed decision;
- Begin the form with a concise and focused presentation, one that facilitates comprehension, of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate.
- Provide information in sufficient detail, presented in a way that does not merely provide lists of isolated facts, but rather facilitates understanding of the reasons why one might or might not want to participate.
- Do not include any exculpatory language through which the subject or the LAR is made to waive or appear to waive any legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Basic elements (b):

- 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 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;
- A 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;
- 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;
- 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;
- 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; and

- One of the following statements about any research that involves the collection of identifiable private information (IPI) or identifiable biospecimens (IB):
    - Identifiers might be removed from the IPI or IB and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research without additional informed consent from the subject or the LAR, if this might be a possibility; or
    - 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.

Additional Elements (when appropriate) (c):

- 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 LAR'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).