**Informed Consent Process**

(a) When informed consent is required, researchers enter into an agreement with research subjects or their legal representatives that clarifies the nature of the research and the responsibilities of the investigator prior to conducting the research.

(b) When informed consent is required, researchers use a language that is understandable to, and respectful of, research subjects or their legal representatives.

(c) When informed consent is required, researchers provide research subjects or their legal representatives with the opportunity to ask questions about any aspect of the research, at any time during or after their participation in the research.

(d) When informed consent is required, researchers inform research subjects or their legal representatives of the nature of the research; they indicate to subjects that their participation or continued participation is voluntary; they inform subjects of significant factors that may be expected to influence their willingness to participate (e.g., possible risks and benefits of their participation); and they explain other aspects of the research and respond to questions from prospective subjects. Also, if relevant, the researchers explain that refusal to participate or withdrawal from participation in the research involves no penalty, and they explain any foreseeable consequences of declining or withdrawing. Researchers explicitly discuss confidentiality and, if applicable, the extent to which confidentiality may be limited as set forth.

(e) When informed consent is required, researchers keep records regarding said consent. They recognize that consent is a process that involves oral and/or written consent.

(f) Researchers honor all commitments they have made to research subjects as part of the informed consent process except where unanticipated circumstances demand otherwise as set forth.