



## **GUIDELINES FOR THE INFORMED CONSENT FORM**

A copy of the informed consent form for the research project must be included with the GRIC RRC application. The informed consent form must fully describe the procedures to be used to protect study participants from injury, harm, or breach of confidentiality. Furthermore, the informed consent form must be written in plain English, which clearly defines all scientific, medical, or health care related terms so that it can be understood by a layman or someone without specialized knowledge or expertise in the health or medical care field. Informed consent seeks to ensure that prospective participants will understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate.

No investigator may involve a human being as a participant in research unless the investigator has obtained the legally effective informed consent of the participant or the participant's legally authorized representative. Informed consent is a process that goes beyond asking for the participant's signature on an informed consent document; it is an ongoing, interactive exchange of information that begins with the initial recruitment of the participant and continues through the completion of the study.

If the study includes biological samples the informed consent must include the following terms: participant must indicate whether he/she wants samples returned or destroyed; if samples are returned then indicate heir, indicate if none then returned to Community; participant may have samples destroyed or returned upon death of the participant.

In the case of a child, only the parent(s) or the legal guardian can provide consent.

The GRIC RRC has the authority to observe, or have a third party observe, the consent process.

Informed consent may not include exculpatory language through which the prospective participant or his or her representative is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release any investigator, sponsor or institution or agents from liability for negligence. The informed consent process is always explained orally to participants, with the informed consent form documented in writing with the signature and date of the participant or legally authorized representative along with the investigator's signature and date.

The informed consent form must include the approval date and expiration date. The informed consent may be withdrawn by the participant at anytime and expires when the protocol approval period expires at midnight on the date of expiration.

During the course of the study it may become necessary to change some of the information in the informed consent form. The informed consent form can be changed by a consent form revision, addendum, or notification to participant or his or her legally authorized representative. Any revisions to the informed consent form must be submitted to the GRIC RRC for review and approval prior to use.

The following information must be included in your informed consent form:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the participant's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the participant;
3. A description of any benefits to the participant or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;
5. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;
6. For research involving more than minimal risk (minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests), 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;
7. An explanation of whom to contact for answers to questions about the research and research participant's rights, and whom to contact in the event of a research-related injury to the participants;
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled;
9. The approximate number of participants involved in the study;

10. The procedures for orderly termination of participation by the subject, and the consequences of a participant's decision to withdraw from the research;
11. Any additional costs to the participant that may result from participation in the research;
12. Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the subject's consent;
13. When appropriate, a statement that the particular treatment or procedure may involve risks to the participant (or embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
14. When research protocol involves biological samples, a statement that the participant must designate to have their biological samples destroyed or returned to the participant or the participant's heir, or if none then to the Community; and the option to have samples destroyed or returned upon death of the participant; and
15. Identify the research project contact for the Community as the GRIC RRC.