Obtaining Consent of the Participant

The goal of the IRB is to protect the rights and welfare of research participants. Obtaining the consent of a participant in research, is a critical part of the research process. The Informed Consent form is part of that protection process. The participant should be fully aware of what they are ***volunteering*** for and what will be expected of them.

The following guidelines are designed to help the investigator solicit and enroll participants in an ethical manner. Following these guidelines may reduce the likelihood of complications during the research process.

Prior to participation in a study, the prospective participant must be briefed about what they may expect to happen during the study. This briefing can be done virtually or in-person as part of the ***informed consent process***.

1) The information provided should be in language that is understandable to the prospective participant.
2) The prospective participant 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. [45 CFR 46]

The IRB cannot approve of a project without a proper ***Informed Consent Form (ICF)*** that includes the following:

A concise and focused presentation of the key information that is most likely to assist a prospective participant in understanding the reasons why one might or might not want to participate in the research that include these *basic elements of informed consent*:

1) 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;
2) A description of any reasonably foreseeable risks or discomforts to the subject
3) A description of any benefits to the subject or to others that 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 subject;
5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6) For ***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;
7) 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;
8) 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 [45 CFR 46]

Prior to any data collection, the prospective participant must first read, understand and be willing to participate in the study.

Anonymous survey research does not require a signature of the participant. Use the ***Example Survey Research Informed Consent Form***.

For all other non-survey research, a place for the participant to sign in agreement to participate is necessary. Use the ***Example Non-Survey Research Informed Consent Form***.