Elements of Informed Consent

Informed consent is the voluntary agreement of a subject to participate in research. More than a signed form, it represents the ethical responsibility of the researcher to ensure that participants have an understanding of the research being conducted and its inherent benefits/risks. Consent signifies that the researcher respects the autonomy of the individual and understands that consent is essential for both the protection of the subject as well as the integrity of the research.

Unless otherwise authorized, the Principal Investigator (PI) is responsible for obtaining the signed informed consent of all participants prior to beginning a study. This procedure is necessary to ensure that only those human subjects who have consented to participate are involved in the research. For subjects under age 18, the researcher must obtain both the signed informed consent of parents (or legal guardians) and the assent of the minor to participate in the study.

Federal regulations, 45 CFR 46 (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html), which are designed to protect human subjects specify that participants in a research study must be given enough information to provide a truly voluntary and informed consent. Subjects must be given the following information in an easily understandable format:

- *Purpose* of the research
- *Procedures* involved in the research
- *Alternatives* to participation
- All *foreseeable risks and discomforts* to the subject including potential physical injury as well as possible psychological, social, or economic harm, discomfort, or inconvenience.
- *Benefits* of the research to society and possibly to the individual human subject
- *Length of time* the subject is expected to participate
- *Person to contact* for answers to questions or in the event of a research-related injury or emergency
- Statement indicating that *participation is voluntary* and that refusal to participate will not result in any consequences or loss of benefits that the subject is otherwise entitled to receive
- Statement regarding the subjects' *right to confidentiality and right to withdraw* from the study at any time without consequences
- Other additional items based on the type of project such as certification of confidentiality or limitation on confidentiality, risks to vulnerable subjects, statement regarding how significant findings will be communicated, payment for participation, and other relevant information.

Waiver of one or more elements of informed consent may be obtained from the IRB for some research projects that could not practically be done without an alteration to the required elements or for studies where required elements are not applicable.