

VI. Informed Consent in Human Subjects Research

Voluntary informed consent is a prerequisite for a subject's participation in research. This section provides an overview of informed consent: its importance, required elements of consent, the consenting process, and documenting consent. Above all, informed consent and the consenting process is about the protection and respect for research subjects.

What is Informed Consent?

Informed Consent is a voluntary agreement to participate in research. It is not merely a form that is signed but is a process, in which the subject has an understanding of the research and its risks. Informed consent is essential before enrolling a participant and ongoing once enrolled. Informed Consent must be obtained for all types of human subjects research including; diagnostic, therapeutic, interventional, social and behavioral studies, and for research conducted domestically or abroad. Obtaining consent involves informing the subject about his or her rights, the purpose of the study, the procedures to be undergone, and the potential risks and benefits of participation. Subjects in the study must participate willingly. Vulnerable populations (i.e. prisoners, children, etc.) must receive extra protections. The legal rights of subjects may not be waived and subjects may not be asked to release or appear to release the investigator, the sponsor, the institution or its agents from liability for negligence.

The Informed Consent is described in ethical codes and regulations for human subjects research. The goal of the informed consent process is to provide sufficient information so that a participant can make an informed decision about whether or not to enroll in a study or to continue participation. The informed consent document must be written in language easily understood by the participant, it must minimize the possibility of coercion or undue influence, and the subject must be given sufficient time to consider participation.

Why is Informed Consent required?

The **Belmont Report** (<http://ohsr.od.nih.gov/guidelines/belmont.html>) and the **Nuremberg Code** (<http://www.cirp.org/library/ethics/nuremberg/>) both address voluntary informed consent as a requirement for the ethical conduct of human subject

research. Informed Consent is the process through which researchers respect individual autonomy, the fundamental ethical principle. An autonomous individual is one who is capable of deliberation and personal choice. The principle of autonomy implies that responsibility must be given to the individual to make the decision to participate. **Informed Consent** means that subjects are well informed about the study, the potential risks and benefits of their participation and that it is research, not therapy, in which they will participate.

The Nuremberg Code states that the voluntary consent of the human subject is absolutely essential not only to the safety, protection, and respect of the subject, insofar the integrity of the research itself.

The Informed Consent Process

Informed consent is more than a form, it is also a process. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. Informed consent process must be a dialogue of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits. The process of consenting is ongoing and must be made clear to the subject that it is his or her right to "withdraw" or "opt-out" of the study or procedure at any time, not just at the initial signing of paperwork. The location where the consent is being discussed, the subject's physical, emotional and psychological capability must be taken into consideration when consenting a human subject. The informed consent process should ultimately assure that the subject understands and really "gets" what they are signing up for.

What elements should be included in an informed consent?

The United States regulations for the protection of human subjects 45 CFR 46 (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>) require whenever human subjects participate in a research study, they need to be given enough information to provide a truly voluntary and informed consent. Subjects must be provided the following information:

- **Purpose** of the research
- **Procedures** involved in the research
- **Alternatives** to participation

- All *foreseeable risks and discomforts* to the subject. *Note: that these include not only physical injury but also 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 any 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 any consequences

Waiver of one or more elements of informed consent may be obtained from the IREC 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.

What additional informed consent elements might be needed for certain projects?

Depending on the project and the subject population, the Informed Consent must also contain information on:

- Certificate of Confidentiality (if any)/limitations of certification protection
- *Payment* for participation (if applicable)
- *Risks* to vulnerable subjects, e.g., embryo, fetus, pregnancy
- *Circumstances* for investigator “withdrawing” the subject
- *Additional costs* from participation
- Early *withdrawal consequences*
- *Statement regarding how* significant new findings will be communicated
- *Number* of subjects participating
- *Probability* of random assignment or placebo placement
- Additional information required by the IREC

Use language that subjects understand / Non-Technical Language

Consent documents **must be clearly written and understandable to subjects**. The language must be non-technical (comparable to the language in a newspaper or general circulation magazine). Scientific, technical, and medical terms must be defined or explained in lay terms. It is often recommended that the informed consent be written at the eighth grade reading level. When enrolling minors in a study, related recruitment materials must reflect the reading level of minors.

Informed consent may **not** include **exculpatory language**, that is, language that appears to waive subjects' legal rights or appears to release the investigator or anyone else involved in the study from liability for negligence.

Furthermore, consent must be provided in the language(s) of the subject. No informed consent, whether oral or written, may include exculpatory language.

Types of Informed Consent

Informed consent and assent templates are available in Appendices B, C, D and E. These templates provide the necessary elements and language for informed consent needs.

Consent – An adult subject, capable of giving permission to participate in a research study, can provide consent. The subject must be at least 18 years of age and competent to make the decision to participate.

Parental Permission – When children/minors are included in research, the parent/guardian must sign a parental permission consent document. Some situations require permission from at least one parent, while other situations require permission from both parents.

Assent – Assent is a child's affirmative agreement to participate in research. If the subject is 7-17 years of age, assent must be obtained. The assent form must be written at the appropriate reading level of the youngest subject in the age range and use simple terminology.

Oral Consent – Oral consent still contains all elements of written consent, however, the participant is verbally read the elements and verbally agrees to participate. Investigators requesting the use of oral consent must provide evidence to the IREC

that the research is “minimum risk” as well as provide detailed reasoning why written informed consent is not a feasible option.