Informed Consent

Subjects participating in research must participate willingly. Informed Consent is a voluntary agreement to participate in research. Obtaining informed consent is a basic ethical obligation and a legal requirement for researchers. The purpose 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. Informed Consent is the process through which researchers respect individual autonomy, the fundamental ethical principle.

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. This requirement is founded on the principle of respect for persons, one of the 3 ethical principles governing human subject research described in the Belmont Report. The principle of respect for persons requires that individuals be treated as autonomous agents and that the rights and welfare of persons with diminished autonomy be appropriately protected. The principle of autonomy implies the responsibility must be given to the individual to make the decision to participate. An autonomous individual is one who is capable of deliberation and personal choice. Vulnerable populations (i.e. prisoners, children, pregnant women, 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 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.

Informed Consent is described in ethical codes and regulations for human subject research; Specifically, in the Department of Health & Human Services (HHS) regulations 45 CFR part 46, and the Food and Drug Administration (FDA) regulations 21 CFR part 50. Except as provided in paragraph "c" of 45 CFR 46.117, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

Both the Belmont Report and the Nuremberg Code address voluntary informed consent as a requirement for the ethical conduct of human subject research. 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, and to such extent or degree the integrity of the research itself.

For studies using Protected Health Information (PHI): Research that is using or disclosing protected health Information must be conducted in accordance with the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA) and requires complete of the HIPAA section of the study application.

Types of Informed Consent

Consent – Informed **Consent** is obtained from adult individuals being asked to participate in a study, capable of giving permission to participate in a research study, can provide consent. The subject must be 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. In some cases, it may be necessary to waive the requirement to obtain parental permission. Refer to 45 CFR 46*subpart D for more information.

Assent – Informed **Assent** is obtained when the research involves minors. A parent or legal guardian must give permission to allow the child to participate in the research, and children who are able to understand information about participation are asked to "assent" or agree to participate as well. 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.

Verbal – Verbal consent still contains all elements of written consent. However, the participant is verbally read the elements and verbally agrees to participate.

Short-Form – A "short form" is generally used when there is a language barrier and an English IRB-approved consent is orally translated in the subject's native language.

Information/Fact Sheet – An information sheet may be used as a form of consent in certain circumstances where a signature could compromise the participant or in studies where signed consent is not required by regulations (research procedures involving minimal/no risk).

Waiver of Documentation of Informed Consent ("Verbal" or "Online" consent) – Waiver of documented consent occurs with participants consent to be in the study, but do not sign a consent form. A waiver of documentation of informed consent can be obtained when the written consent is the only link to the study and record of the subject's name could compromise the participant. In this case a verbal or information sheet can be used, or the consent may be read to the subject. A waiver for documented consent may be requested when the research is associated with minimal risk involving:

- Surveys sent through the mail or conducted over the internet
- Telephone interviews
- The collection of sensitive information without a written record that could identify participants

Waiver of Elements of Informed Consent – A waiver of 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.

Waiver of Informed Consent (research is conducted without obtaining consent from the subject)
A waiver of informed consent may be requested in the following instances:

- Medical chart reviews
- Analysis of existing data
- In rare cases, when secondary participants may be involved, and it would either be prohibitive or potentially dangerous to obtain consent.

The Board may alter or waive the general requirements for consent if the following apply:

- The research involves no more than minimal risk to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation

Broad Consent – A new type of regulatory consent under the Common Rule for non-exempt storage, maintenance, and research use involving identifiable information and biospecimens. Broad consent may be used as a substitute for traditional informed consent in a range of defined circumstances.