Informed Consent Process

Informed consent is the process of learning the key facts about a research study before you decide whether or not to volunteer. Being in a research study is voluntary. You should know what will happen before you agree to participate. Informed consent begins when the research staff explains the facts to you about the research study.

The research staff will go over the study details with you so that you can decide if you want to participate. The process will include details about the research study, procedures you may receive, the benefits and risks, and your rights as a research volunteer.

The informed consent process is more than just reviewing a piece of paper. It is a process that goes on throughout the research study. During the research study, you may be told of new findings, benefits, or risks. At any time, you can decide whether or not to continue to take part in the research study. You may change your mind and leave the research study before it starts. You may also leave at any time during the research study or the follow-up period without penalty.

You should have plenty of time to ask questions. It is your choice to enroll, withdraw, or continue participating in the research. The informed consent process should ensure that all critical information about a study is completely disclosed. You should adequately understand the research so that you can make informed choices.

In many cases, informed consent is documented in writing with a consent form. However, even if a signed consent form is used, it alone is not the complete process. The informed consent process is an ongoing exchange of information between the investigator and you.

Credit: This document is based on the guidance document from OHRP.