# Informed Consent Requirements

## What is Informed Consent?

Essential in the protection of human subjects is that potential participants first **understand** and then **freely consent** to the proposed research project.

The informed Consent is described in ethical codes and regulations for human subjects research; Specifically, Code of Federal Regulations (CFR) Title 21 Part 50.

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.

Obtaining informed consent involves informing the subject about his or her rights, the purposes of the study, the procedures to be undergone, and the potential risks and benefits of participation.

Subjects being studied must participate willingly. 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 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 and the Nuremberg Code 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 the 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, to such extent or degree the integrity of the research itself.

# Types of Informed Consent

**Consent** – An adult subject, 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 others 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** – 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** – 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.

**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.

# Required Elements for Informed Consent

*(Please refer to DHS HHS OHRP 45 CFR 46.116 General requirements for informed consent and 46.117 Documentation of informed Consent)*

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.

| **Basic Required Elements of Informed Consent** *(new elements of 2018 in bold)* | Citation |
|---|---|
| A statement that the study involves research | _.116 (b)(1) |
| An explanation of the purposes of the research | |
| The expected duration of the subject's participation | |
| A description of the procedures which are to be followed | |
| Identification of any procedures which are experimental | |
| A description of any reasonably foreseeable risks or discomforts to the subject | _.116 (b)(2) |
| A description of any benefits to the subject or to others which may reasonably be expected from the research | _.116 (b)(3) |
| A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject | _.116 (b)(4) |
| Statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and what records may be examined by the research staff, IRBs, sponsor, their representatives, and possibly the FDA or OHRP. | _.116 (b)(5) |
| For research involving more than minimal risk, a statement that emergency medical care will be arranged for a study-related illness or injury, and an explanation of whether funds are set aside to pay for this care and/or compensation, and if so by whom (e.g., sponsor, subject, insurer). Language must not be exculpatory. | _.116 (b)(6) |
| Identification of whom to contact (a) on research team with questions, concerns, complaints or about a research-related injury; and (b) at the IRB for same issues and information about research subjects' rights. | _.116 (b)(7) |
| 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. | _.116 (b)(8) |
| • **A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; OR**<br>• **A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed will NOT be used or distributed for future research studies** | **_.116 (b)(9) (i) and (ii)** |
| Identification of funding source(s) | IRB requirement |
| **Additional Elements as Appropriate** | |
| A statement that the particular treatment or procedure may involve risks to the subject (or the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable | _.116 (c)(1) |
| Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent | _.116 (c)(2) |

| | |
|---|---|
| Any additional costs to the subject that may result from participation in the research | _.116 (c)(3) |
| The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject | _.116 (c)(4) |
| A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject | _.116 (c)(5) |
| The approximate number of subjects involved in the study | _.116 (c)(6) |
| A statement that he subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit. | _.116 (c)(7) |
| A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and | _.116 (c)(8) |
| For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen) | _.116 (c)(9) |
| If monetary payment will be given, a statement informing the participant that their personal information (name, address, and social security number) will be collected for tax purposes and will be reported to the IRS if they receive over $600 in one year from Emory. | IRB requirement |
| All information concerning payment, including the amount and schedule of payments | IRB requirement |

| **Additional IRB Requirements** |
|---|
| In the case of minors (< 18yrs), the assent form is worded in age-appropriate reading level of the youngest subject in the age range and use simple terminology |
| A signature line for the subject, date of signature, printed name of the subject |
| A signature line for the principle investigator and date of signature |
| A witness' signature line |