Informed consent in research: Everything you need to know

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A voluntary decision to participate in research is *informed consent*. It is not simply a signed *informed consent form*, however, a process wherein the participant has an awareness of the research as well as its risks. Therefore, for a participant's involvement in research, voluntary *informed consent* is a prerequisite. For all kinds of research on human subjects, *informed consent* must be obtained.

Consent happens when one person freely agrees to another's request or wishes. The Belmont report (http://ohsr.od.nih.gov/guidelines/belmont.html) address voluntary informed consent as a requirement for the ethical conduct of human subjects' research. It is a common phrase with unique meanings that are used in areas such as research, and sexual relations. Consent can vary from its regular sense, as understood in particular contexts. An individual with a mental illness, a low mental age, or under the legal age of sexual consent, for example, can voluntarily engage in a sexual act that still fails to satisfy the legal consent threshold as specified by applicable law.

The purpose of the process of *informed consent* is to provide enough information so that a participant can make an informed decision on whether or not to enrol or continue to participate in a study. The *informed consent form* should be written in a clear language easily understood by the participant, the risk of intimidation or outsized influence must be minimized, and adequate time must be given to the participant to consider participation.

The *informed consent* process must be a dialogue about the intention, duration and purpose of the research. The consent process is ongoing and it must be made clear to the participant that it is his or her right at any time, not just at the initial signing of the paperwork, to cancel or opt-out from the study. Ultimately, the mechanism of *informed consent* should ensure that the subject knows and truly gets what they are signing up for.

Types of *informed consent*

Below are some of the types of *informed consent*.

Consent – An adult subject who can permit to participate in a research study can give consent to a research study. The subject must be 18 years of age and competent to decide to participate.

Parental Permission - When children or minors are included in the research, the parent/guardian must sign a parental permission *informed consent form*. 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.

Verbal – Verbal consent still contains all elements of written consent, however, the participant is verbally read the elements and verbally agrees to participate instead of signing an *informed consent form*.

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 subjects 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.

The information sheet may be used as a form of consent in exempt studies for which signed consent is not required by regulations and also in certain circumstances when a signature could compromise the participant. Below is a template for an information sheet and a sample information sheet from a summer trainee project.

Information sheet template

Study Title: Generic Title

Date: 28/09/2020

You are invited to participate in a research study conducted by **_(Who)_____** from the Industrial Psychology Consultants.

We are asking you to take part in this study because**__(Purpose/brief description of study)_.**

Your participation is voluntary and would consist of **__(Provide procedures & length of time it will take)_**.

There are no anticipated risks to your participation and there are no direct benefits to you for taking part in this study **(Or explain possible risks/benefits if applicable)**.

You will receive **__(provide the description)_** for your participation. You will be given a copy of this form.

If you have any questions about this research study, please contact **_(Provide contact information**)_.

Exceptions

Cases where 'implied consent' may be acceptable (for example online surveys)

Researchers should always aim to inform people fully and obtain appropriate consent. However, in some cases, the research may be straightforward enough that a separate, deliberate process for obtaining consent is not needed. In these cases participants, by their actions, imply consent. This is seen most often in research:

where researchers have no direct contact with participants, for example, a research survey deployed via an online survey platform; where no participant personal details are obtained; where the topic of research is very low risk and no sensitive data will be collected; and where participation is confined to one small task, for example completing a survey or simple pencil or computer task.

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https://thehumancapitalhub.com/articles/Informed-Consent-In-Research-Everything-You-Need-To-Know