Informed Consent

Informed consent is a person’s voluntary agreement, based on an understanding of the relevant information, to participate in research or a clinical trial, or to undergo a particular medical intervention.

Before any research may be carried out, participants must be informed about all aspects of the study and/or intervention, including the aims, methods, anticipated benefits, and potential risks. Participants must also be made aware that they can withdraw from the research at any stage without any negative consequences to their ongoing care or treatment. This information must be given in an accessible and understandable way (for instance via a participant information sheet), and individuals should be given the opportunity to ask questions about the research.

Informed consent is usually documented in writing with a signed and dated consent form. However, informed consent should be an ongoing process throughout a study, and researchers should ensure that participants are made aware of any new information which might influence their decision about whether to take part or not.

In rare circumstances (for example, when an individual may not be able to give informed consent), the usual practices for informed consent may not be possible. Researchers may obtain delayed consent (for instance, for research into emergency situations) or consent by proxy (when the ability to consent is delegated to someone else). In some cases informed consent may be implied by a person’s actions or inaction or silence.