

What is a Consent Form?

Consent in a medical context, as in every day life, means permission. For small things like having your blood pressure taken consent is verbal or implied by co-operation. For certain procedures like an operation or before involvement in a clinical trial, where there are important implications and potential risks, consent is taken formally. Both the patient and the person taking consent sign a 'consent form' to say they have agreed on a proposed action, usually a treatment. This is a contract giving permission to the health care professional to proceed with treatment. After all, performing an operation without a patient's consent could be considered an assault.

Criteria for consent

Someone signing a consent form does not guarantee meaningful consent. The patient must be deemed able to understand what is proposed, retain the information, be able to weigh up the alternatives and understand the consequences. This means patients who are confused, intoxicated or suffering from a neuropsychiatric disorder e.g. dementia are unable to provide consent meaningfully. Similarly, consent should be given entirely through free will without coercion or pressure from others. If circumstances allow, time should be allowed to consider the proposed treatment before consenting.

Consent in special circumstances

If patients do not have the capacity to consent (for the reasons above) the medical team must act in the patients best interests consulting with family when possible. Consent in those under 18 years of age can also raise particular issues.

Informing the patient

Understanding of medical matters and the likely comprehension varies widely in members of the public. Some people want to be fully informed and involved in decision making and some do not, so the approach must be tailored. In general, this should include a description of what will happen, the risks that are common (e.g. in more than one per hundred cases) or serious such as stroke or death (even if rare).

Consent to participation in research

The same consent process is necessary to allow participation in research. All clinical trials in the UK are evaluated and approved by an external body called an ethics committee. They review everything down to the information sheet you receive and the consent form you sign. Responsibility for running the trial rests with the hospital trust.

What consent does not mean

Despite signing the consent form the patient still has the right to change their mind at any stage. The right to complain or seek compensation subsequently is unaffected. The consent process formalises an agreement and protects both doctor and patient.

Author: Dr Ross Hunter, Cardiology Research Fellow
Professor Richard Schilling, EP
Endorsed by: Dr Matthew Fay, GP
Dr Andrew Grace, EP
Mrs Jayne Mudd, Arrhythmia Nurse Specialist
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