

The Process of Informed Consent.



Informed Consent



ICH GCP(1996) 1.28, defines Informed Consent as:
"A **process** by which a subject **voluntarily** confirms his or her willingness to participate in a particular trial, after having been **informed** of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is **documented** by means of a written, signed and dated informed consent form.



Remember the person at the centre of the process.

1 An Ongoing Process

rather than a one-off event.

2 Voluntary Participation

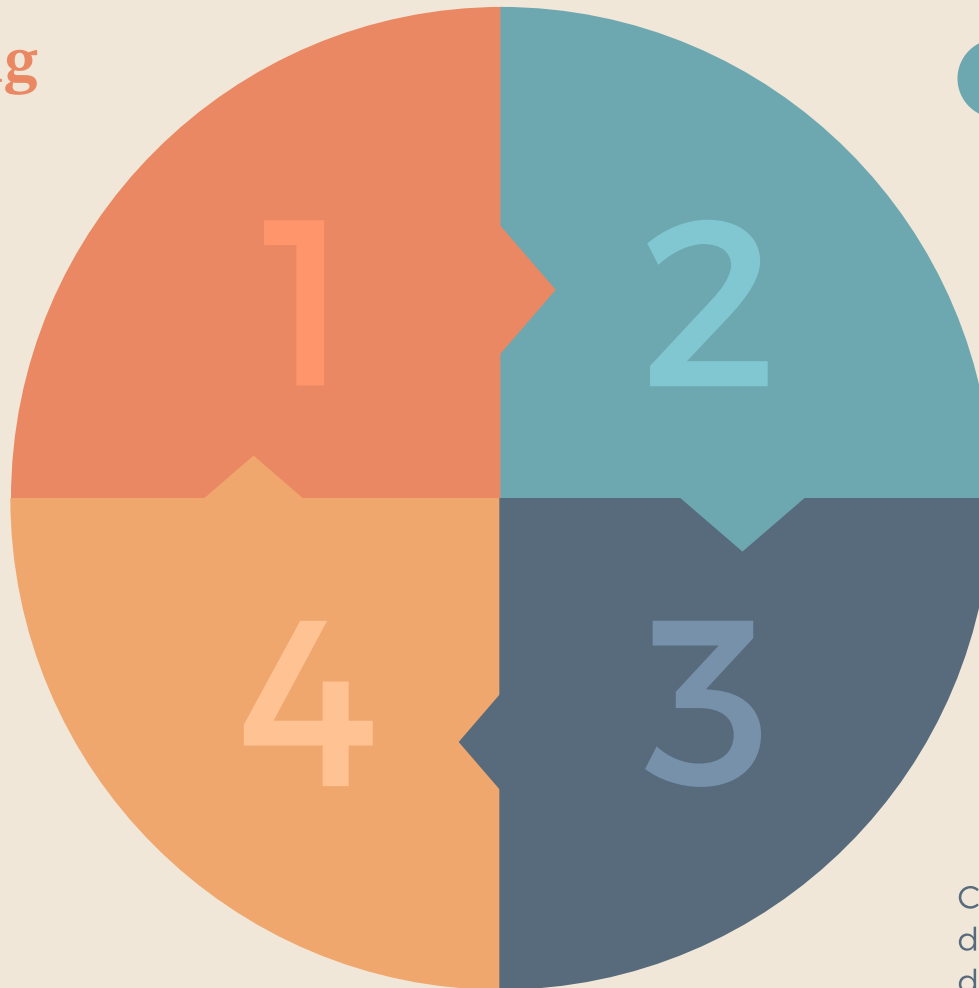
Don't have to provide an explanation for saying 'no'

4 Informed Decision

Relevant approved information explained and discussed and questions answered

3 Process Documented

Consent formally documented via signed & dated consent form. Full process/details recorded in notes.



Can it translate into everyday practice?

Although the ethical considerations and the fundamentals of the informed consent process which underpin good practice, are common to all types of clinical research, there is nothing to suggest that these same principles can not be used and be part of everyday clinical practice.



Imagine a scenario where you the patient are the centre of all your care, where your willingness to participate in all aspects of your care is always actively sort and your participation is recognised as voluntary without you having to give a reason as to why you are declining any part of said care/treatment, information about any part of your care/treatment is clearly explained and discussed with you with provisions for you to be able to involve family members in the discussions as well as other healthcare professionals before making a decision and the whole process including your consent is formally documented. With the whole process repeated each time you accessed healthcare!





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"expertise in action"

'The process of Informed Consent'-
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