Module Summary: The Process of Informed Consent

The fundamentals of the informed consent process and the ethical considerations which underpin good practice are common to all types of clinical research. What we have covered in this module is only part of the story of good practice in informed consent; we have explored the requirements but not the communication skills required to support potential participants in their decision making.

We suggest you explore other training options to support your practice, such as being observed or observing colleagues as well as courses and workshops. Further training is also available on the specific requirements for studies involving children and adults lacking capacity. See the NIHR CRN website for further information: https://www.crn.nihr.ac.uk/learning-development/

Informed Consent

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.

1.28, ICH GCP (1996)

An ongoing process

Informed consent is an ongoing process, rather than a one-off event. The process begins with a discussion with the potential participant about the study. Consent must be received before any study related procedure takes place. Ongoing willingness to continue in the study should be sought each time you see the participant and documented in their patient notes.

Voluntary participation

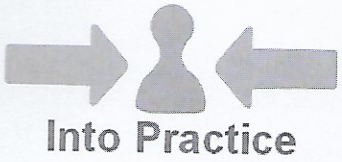
It is important that you are comfortable and confident that the potential participant is giving their consent freely and has understood the information discussed; that they are making an informed and voluntary decision. In a voluntary process, some participants will say 'no' to participating in research, and they do not have to provide an explanation for their decision.

Informed decision

The Sponsor will provide you with a Patient Information Sheet, approved by the Research Ethics Committee, which sets out the information you must explain and discuss with the potential participant. The person being invited to participate may have additional questions about the research or the study processes in addition to what is included in the Patient Information Sheet. They may also wish to discuss the study with other people such as family members or other health care professionals before making their decision.

Document the process

Once the person being invited to participate has decided they do wish to join the study, their consent must be formally documented through a signed and dated consent form. Full details of the process should also be recorded in the participant's patient notes. Participants do not need to provide an explanation for their decision to participate in the study or not, but may volunteer their reasons which should be documented in their notes.



These tips and ideas will help you deal with the practical challenges of applying GCP to real studies in every day practice

Remember the person at the centre of the process

Each potential participant's individual needs and circumstances need to be taken into account. It is important to give people the opportunity to participate in research for which they may be eligible, and to enable them to make a voluntary, informed choice about whether they would like to.

Look at the ICH GCP E6 Guideline

Section 4.8 of the E6 Guideline provides an excellent practical guide to the process of informed consent which is relevant to all studies, whatever their methodology. A particularly useful section is 4.8.10 which provides details of the information which should be provided to participants in both the written Patient Information Sheet and in discussion. Access the guideline at http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/good-clinical-practice.html

Are you competent and confident to carry out your role in the process?

Do you understand the study? Do you know what the participants will be required to do? Are you aware of the potential risks and benefits? To enable potential participants to make an informed choice you need to be able to deal with their questions effectively and provide them with answers.

Observe colleagues during the consent process

Providing you have the permission of the person being approached to join the study, a good way to learn about the process of informed consent is to observe a more experienced colleague. It may be useful to observe a visit during the study as well as the initial discussion of the study to see how they check the participant's ongoing willingness to participate.

Ask a colleague to observe you

Asking someone to observe you and provide feedback is an excellent way of finding out if you are explaining the study and its requirements as clearly as you can, and to get some pointers on where you might improve your practice. It is also a way in which the PI, or someone acting on their behalf, can ensure compliance with the Protocol and GCP. Again this should be done with the permission of the potential participant.

Consider the practicalities

- How much time is allowed for discussion of the study with a potential participant? Where will the discussion take place? What documents do you need to have with you to support the discussion? Do you have the correct versions?
- When do you need consent for each study? At what point should the study be introduced and at what point does the consent form need to be completed before going any further?
- Where will you copy the signed consent form? Will a number of copies be completed or will they be photocopied? How far will you need to go to copy the form? Impractical solutions lead to forms being lost or copies not being provided to the participant. Ensure your systems support compliance with requirements.