Research & Innovation
Research Governance Framework Factsheet

Informed Consent

What is Informed Consent?
Valid informed consent for participation in research must be given voluntarily. Adequate information must be provided to ensure the decision to participate is fully informed and consent must be taken by appropriately qualified individuals. Requests for informed consent for research should avoid any form of coercion and the process must be recorded in writing. See the Declaration of Helsinki.

Voluntary
Potential participants should understand that they are free to withhold consent and that doing so will not affect the standard of treatment they receive or upset the people responsible for their healthcare. Assurance should be given that once enrolled in a study, participants may withdraw at any time, without having to give a reason.

Information
Potential participants must have a clear understanding that they are being asked to take part in research. Where one exists, the alternative standard treatment should also be explained. The purpose of the study, together with the actual and potential risks should be discussed. Arrangements for confidentiality and anonymity must be described, including who will have access to the participant's data. Investigators should disclose who is funding and/or sponsoring the research, that participants will not be identifiable from publications and whether or not travel expenses will be paid.

Competence
Special requirements apply to research involving children, adults whose competence is compromised and other vulnerable groups. Contact the Health Research Authority for advice when planning research with these groups or the Centre for Ethics in Medicine, University of Bristol.

The reasons for not obtaining informed consent for any research study must be documented in writing and submitted to the Health Research Authority for consideration.

In Writing
Informed consent is a process, not a signature on a form. The consent form indicates that there has been full discussion of all relevant facts with time and opportunities for the potential subject to ask questions. Signed consent forms should be witnessed and dated. A copy should be given to the participant with the Information Sheet and the original stored either with the raw data for the study or in the patient's medical records for an appropriate retention period as stipulated by study type and GCP requirements. One reason for doing this is to ensure that proof is available that informed consent was given should it be questioned at a later date.

The investigator is responsible for assuring the adequacy of informed consent from or on behalf of each participant. Although the investigator may delegate another appropriately qualified person to obtain consent from prospective participants, the responsibility remains with the investigator.

Why is Informed Consent in Research so Important?

"The dignity, rights, safety and wellbeing of participants must be the primary consideration in any research practice"

All studies must have appropriate arrangements for obtaining consent and the ethics review process will pay particular attention to those arrangements.

When is it necessary to obtain informed consent?

Informed consent should be sought for all research where it is practicably possible. In circumstances where consent is not possible a detailed explanation will need to be included in the approval paperwork submitted to the Health Research Authority for their consideration as to whether the reasons for not taking consent are justifiable.

Tips for Good Practice

- Encourage the presence of a friend or relative in the informed consent interview
- If possible offer to tape record the interview for the patient to take away
- Where randomisation is to take place, pay specific attention to ensuring that potential subjects understand the implications of this
- Guard against creating false hope and unrealistic expectations of a new treatment or drug. Not doing so can cause disappointment and resentment later
- Thank people for their participation