How to guide: Receiving consent

This guide outlines some general guidance on receiving consent.

Key information you should be aware of:

Informed consent is a fundamental principle of research and it is vital that consent is given freely, with full information of what a participant is consenting to being provided. Either the participant must have capacity to consent or it must be received by means of a process involving a consultee or legal representative (where this is appropriate and allowed for in the study). Consent should be received only by a member of staff who is appropriately trained and approved to do so. Consent may be withdrawn.

- The practice is responsible for ensuring that all staff who may be involved in a study have an understanding of what is involved.
- All staff involved in the consenting of patients will need to complete Good Clinical Practice (GCP) training.
- All staff involved in research at the practice must have completed study specific training where this is required for the study.
- Consent must have been received before any research activity relating to the patient and/or their personal data takes place.
- The consent process must be conducted in line with GCP principles and the study protocol.

Highlights

- Preparation
- Consent process

See also

- Getting your practice ready to do research guide
- Roles and terminology guide
- Site selection / initiation visit (SiV) guide

Full guide

Preparation

- The Health Research Authority (HRA) approvals process includes ensuring that the consent process for approved research is ethical and legal. Therefore, it is vital that the consenting of participants is carried out in line with what is stated in the current HRA approved study protocol.
- Staff involved in the consenting of participants must be:
    - GCP trained and have a certificate that is recent enough for the requirements of the study (usually within 2 years – if in doubt, this should be checked with the study team);
    - adequately qualified as outlined in the study protocol or by the study team (this may be specific to particular studies i.e. some studies may require that the consenting of participants must be done by a nurse or GP);
    - approved to do so by the Principal Investigator of the local site (GP practice) and this must be included in the Delegation Log.

Consent process

- Participants must be fully informed and in a position to consent (having capacity to consent or by means of a process involving a consultee or legal representative where this is appropriate and allowed for in the study). See the study protocol guide for further information.
- Consent must have been received before any research activity relating to the patient and/or their personal data takes place.
- Consent must be documented and filed in line with the study protocol.
- Since consent is an ongoing process, staff involved with study participants should ensure they are happy to continue during study follow-up visits etc. and must respect any wishes to withdraw consent.

Further general guidance on the subject of consent in research can be found online: Getting informed consent for user research - Service Manual - GOV.UK (www.gov.uk)

Glossary of Acronyms and Terms

HRA	Health Research Authority
GCP	Good Clinical Practice