SOP 25 Associated Document 1: Informed Consent Guidance

Contents

Purpose:

The guidance covers consent (including e-consent) in adults, children, young people and adults not able to consent for themselves (in both emergency and non-emergency situations), healthy volunteers and takes into account UK-wide requirements.

Who can take consent:

All staff delegated by the PI as able to take consent from participants must be listed on the study delegation log which is signed by the PI. Delegated individuals should be appropriately trained and qualified.

When delegating the taking of consent, individuals must be:

- Suitably trained and qualified.
- Familiar with all aspects of the study as described in the latest approved version of the protocol. This should include enough knowledge of the proposed investigation, treatment and / or condition and an understanding of the risks of the study in order to answer questions raised by the participant.
- For MHRA regulated studies, be familiar with the latest version of the Investigator Brochure (IB) or Summary of Product Characteristics (SmPC) as applicable.

Consent must be obtained prior to participation in the research study. For example:

- Before initiation of any screening procedures.
- Before any changes are made to the participant's medication.
- Before any preparation for screening procedures, e.g. before fasting for blood draws.

Best Practice for taking consent

Unless otherwise agreed by the Sponsor, the following is deemed as best practice:

The potential study participant will be identified and approached by a member of their direct care team (DCT), please seek advice from the JRMO or see the Joint Research Management Policy for Barts Health definitions and standards on who is deemed to be part of the DCT. A member of the DCT will then approach/contact the participant about the research study.

- A study physician (MHRA regulated) or suitability trained member of the research team (Interventional and Research studies) must ensure each participant meets the eligibility criteria BEFORE they are entered into the research study.
- The potential study participant, or their legally acceptable representative, will then be informed of all aspects of the research study (including the nature, significance, implications/burdens and risks of the research) in a way that they are able to understand, both verbally and in writing, in the form of the PIS.
- The potential study participant or their legally acceptable representative must be given as much time as they require to read the PIS and to ask any questions prior to making a decision to take part in the research study. The potential participant must be given a copy of the PIS to take away with them.
- If the participant agrees to take part in the study, the person taking consent must ensure the participant understands the research study, that participation is voluntary, and that they know they have the right to withdraw from the study at any point without their care being affected.

It is good practice not to recruit anyone who could be “coerce[d] or unduly influence[d] to participate or to continue to participate in a study”.

Family members of the research team or closely associated staff (i.e. people over whom there is the potential for the CI or PI to have undue influence) should not be recruited onto a study unless specifically approved by the ethics committee.

HTA Exceptions

Research involving human tissue (from the living and/or the deceased) requires specific consent for the samples to be stored and used in research. For this, tissue samples must be transferred and stored in a Human Tissue Authority (HTA) Licensed Tissue Bank after the ethical approval has expired.

1. Consent is not required if the samples (from the living and/or the deceased) were taken before 1st September 2006.
2. Consent is not required from a living donor fully anonymised to the researcher and where the study has REC approval.

An HTA license is not required where samples are being stored for use in a specific REC approved study and the tissue is not retained after that study for unspecified future use.

Filing of ICF and PIS

After signature, the original ICF must be kept in a safe place; It is recommended that (where Barts Health is a site) a verified scan of the Signed Consent form and relevant PIS are uploaded on to Barts Health Main electronic health record system [Millennium] and that the original is kept in the Investigator Site file. A copy must always be given to the participant (along with a copy of the associated PIS).

It is permitted however that it is kept either in the participant's medical notes (where applicable), with source documents, or in the study file (with a copy placed in medical notes / with source documents) with a copy of the PIS and ICF must be filed in the medical notes/with source documents and the Investigator Site File (ISF).