

# Guidance document for researchers

## Obtaining informed consent for studies sponsored solely by the Trust or jointly with the University

*This 'best practice' document is to be used by researchers when taking informed consent. It has been written to comply with relevant regulations and guidelines. The content should be reviewed in conjunction with any guidelines/procedures which are unique within your department.*

Any person who will play a role in the consent process must have a comprehensive understanding of the study, potential treatment toxicities (in the case of clinical trials), other safety implications and the associated disease area. They should be qualified by experience and should have received appropriate training for this study. All training should be documented.

The delegation of Informed Consent to an appropriate, suitably qualified member of the research team should be considered on a trial-by-trial basis, taking account of local circumstances and in accordance with ICH Good Clinical Practice Guidelines. An effective line of communication should always be maintained back to the Chief/Principal Investigator who is ultimately responsible for the subject's care.

Delegation of responsibility for aspects of the informed consent process should be documented on the appropriate form which should be filed in the Trial Master File (TMF) or Investigator Site File (ISF).

It is the responsibility of the investigator or delegate to ensure that subjects have fully understood what they are consenting to.

### **Consent form and participant information sheet**

These documents should be created based on the guidance on the National Research Ethics Service website - <http://www.nres.npsa.nhs.uk/rec-community/guidance/#InformedConsent>

Any consent forms that exist for non-research purposes should not be used.

### **Informing the subject**

The subject must sign the informed consent form prior to any study related procedures being carried out. The informed consent process should continue throughout the study, keeping subjects informed of any protocol amendments or new information which the investigator feels is relevant to them.

The subject should be given ample time to read the information sheet. This should always be the most recent version which has been approved by the ethics committee. They should have as a minimum, the length of time stated in the ethics application form, to discuss the information with family and friends etc.

The subject should have an interview with the investigator or another member of the team in which they are given the opportunity to understand the objectives, risks and inconveniences of the trial and the conditions under which it is to be conducted. They should then have an opportunity to ask questions of the investigator or delegated representative.

Neither the investigator nor any member of the clinical research team should coerce or unduly influence a subject to participate or to continue to participate in the trial. It should be made clear to the subject that declining to take part in the study will not affect their future care or treatment and that they are free to withdraw from future involvement with the study at any stage without providing a reason.

If changes are made to the information sheet and/or consent form during the study, which are considered relevant to subjects who have signed the previous version and are still participating in the study, they should be asked to also sign the new version to ensure that they are willing to continue under the new conditions.

### **Recording Informed Consent**

When the person taking consent is satisfied that the subject has been fully informed and understands what study participation entails, the subject should initial the boxes on the consent form and then sign, date and print their name. The person taking consent should then do the same.

Two copies of the signed and dated consent form should be made. The original should be filed in the relevant section of the TMF, a copy should be given to the subject and a copy should be filed in the subject's medical records. Copies may also be required by the co-ordinating centre, in a multi-centre study, however **prior consent should be obtained before passing identifiable data to any third party.**

Copies of consent forms signed by subjects who do not go forward to participate in the study should also be kept in the TMF and not discarded.

### **Confidentiality**

No identifiable data should be passed to a third party without the prior consent of the individual, this includes faxing of consent forms. It is preferable that only anonymised data is sent outside the Trust.

### **Incapacity**

In the case of participants and potential participants in Clinical Trials which are subject to the Medicines for Human Use (Clinical Trials) Regulations 2004 and who lack capacity to consent (such as minors and incapacitated adults), researchers must obtain informed consent from a personal legal representative, or if no such person exists, a professional legal representative. Such legal representative must not be connected with the clinical trial.

All other research involving participants who lack capacity to consent is governed by the Mental Capacity Act 2005. Researchers must appoint a consultee. Arrangements for nominating a consultee should be addressed when applying for REC approval. A person with a professional relationship to the participant may act as a consultee provided they have no connection with the research.

The Trust's policy for obtaining consent can be found at <http://connect/index.cfm?articleid=7944>