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Appendix 1: Information to be provided to potential trial subjects
1. Introduction

Informed consent is the process by which a subject voluntarily confirms their willingness to participate in a research study having been informed of all aspects of the study that are relevant to their decision to participate.

Informed consent is an ongoing process. It involves giving information to the subject, discussing and clarifying the information, seeking the subject’s written consent and subsequently providing any new information that might affect the subject’s willingness to continue to participate in the study.

Consent is documented by means of a written, signed and dated informed consent form. Further information on designing appropriate patient information and consent forms is available on the HRA website.

In obtaining and documenting informed consent, the Research Team must comply with Good Clinical Practice and with the ethical principles that have their origin in the Declaration of Helsinki.

1.1 Purpose

To describe the processes for seeking informed consent to enter a research study, and for documenting that consent has been obtained.

2. Roles and Responsibilities

2.1 Duties within the Organisation

It is the responsibility of the Research & Innovation Office to make Trust R&I SOPs available to all research active staff working on Trust-approved research studies.

It is the responsibility of the study Chief Investigator (CI) or local Principal Investigator (PI) to ensure that up-to-date copies of Trust R&I SOPs are available to research staff.
It is the responsibility of the study Chief Investigator or local Principal Investigator to ensure up-to-date SOPs are filed in the Investigator Site File and are available to research staff, and to inform the Research Support Co-ordinator of the names of all research staff involved on a study so that copies of SOPs can be distributed appropriately.

It is the responsibility of the study Chief Investigator or Principal Investigator to designate if the SOPs of another organisation are to be followed for a study. For example those of a Clinical Research Network or commercial sponsor. If there is significant conflict between the external SOP and the Trust R&I SOP it is the responsibility of the CI or PI to resolve these with the Research Office prior to starting the study.

It is the personal responsibility of all staff to follow Trust (or the designated alternative organisations) procedural documents.

The Research & Innovation Office is responsible for managing Trust R&I SOPs including their approval, dissemination and archiving. All Trust R&I SOPs must be made available via Q-Pulse and published on the Trust website.

### 2.2 Specific to this SOP

Overall responsibility for all elements of research activity, including seeking informed consent, rests with the local Principal Investigator (PI).

It is considered best practice that only those involved directly with the participant’s care, and with good knowledge of the study, should seek consent. In particular, those seeking consent must have sufficient knowledge of the study procedures and the investigational medicinal product (if applicable), and must understand the risks involved, in order to provide any information the subject may require. If the task of seeking informed consent is delegated to another member(s) of the research team, it is the responsibility of the PI to ensure that the individual(s) is/are suitably trained and qualified.

In the case of a Clinical Trial of an Investigational Medicinal Product (CTIMP) the person seeking consent should normally be a qualified physician, unless agreed by the main Research Ethics Committee and the Research Governance Sponsor.

Where applicable, it is the responsibility of the PI to ensure that the delegation of the task of seeking consent is clearly documented.

It is the responsibility of the person seeking consent to ensure that they have provided a copy of their signed and dated CV for the Investigator Site File, and have completed and signed the Delegation of Duties Log.
It is the responsibility of the person seeking consent to ensure they are fully familiar with all aspects of the study as described in the latest version of the protocol and approved by the Research Ethics Committee (REC).

3. Seeking Informed Consent

All information presented to subjects in relation to the research in any format (written documents, CDs, DVDs etc.), including the Patient Information Sheet (PIS), consent form and any study advertisements, must have prior ethical approval and should be version numbered and dated.

The subject should be provided with ample time and opportunity to read the written PIS and to discuss the study with family or friends before being asked to sign the consent form. Generally, this should be at least 24 hours, however, following a debate between 24 Research Ethics Committees the National Research Ethics Service stated a timeframe of 24 hours is not always helpful and time given to consideration needs to be thought through for each study (see section 7). The timeframe for consent must be stated on the Ethics application and approved by the Ethics Committee.

Prior to signing the consent form, the subject should be given opportunity to ask questions of appropriate members of the research team and if required should be given further opportunity to consider their involvement, and to ask questions.

Consent forms must be completed prior to any study-related procedures being conducted. The timing of the signing of the consent form relative to study registration and the initiation of study procedures is subject to scrutiny. It is therefore essential to record dates correctly on both the consent form and in the subject’s medical notes.

If the subject does not speak English or has hearing loss and requires an interpreter, it is best practice to use an independent translator, as opposed to a family member. If written information is to be translated into other languages it is advisable to obtain a certificate of assurance that the translation is correct.

Any information imparted to the subject (written or verbal) should not contain any language that causes the subject to waive (or appear to waive) any legal rights, or that releases (or appears to release) the investigator, institution or sponsor from liability for negligence.

Neither the Investigator nor any member of the clinical research team should coerce or unduly influence, by any means, a subject to participate or to continue to participate in a trial.
A full list of information that should be included in any explanation to a potential subject, as specified by GCP Guidelines can be found in Appendix A.

The practice of giving information about the study to subjects should be an ongoing process performed by all members of the research and/or multidisciplinary team.

4. Documenting Informed Consent

The consent form must be printed on the headed paper of the Trust where the participant is being recruited.

The consent form must make reference to the version number and date of the PIS that the subject has been given.

The consent form must only be completed once the person seeking consent is satisfied that the subject has been fully informed and understands what study participation entails.

The subject should initial (rather than tick) against each statement on the consent form to indicate their agreement. This must not be completed by the Investigator on behalf of the subject.

The consent form must be signed and personally dated by the subject and the authorised person who conducted the informed consent discussion. The form should be signed by both parties on the same date unless specified otherwise in the Protocol and approved by the Ethics Committee. Each should also clearly print their name by their signature. The Investigator must not complete any of the information on behalf of the subject.

The process of seeking informed consent must be documented in the subject’s medical records (if applicable), detailing the study title and/or acronym, the version number and date of the relevant PIS and the date that consent was obtained. The entry should be dated and electronically signed by the person authorised and responsible for conducting the informed consent process.

Two copies of the original signed and dated consent form should be made, the original should be filed in the Investigator Site File, a scanned copy can be placed in the electronic patient record, and a copy given to the subject.

Subjects should be given copies of all relevant, updated and new, information regarding the study throughout their participation, once this information has received ethical approval.
5. Re-consent

If revisions to the research protocol throughout the course of the study result in changes that may affect a subject’s continued involvement in the study, then subjects must be asked to re-consent.

A revised PIS and Consent Form, appropriately version numbered and dated, must be provided to the subject. All revised documentation must be approved by the REC that originally reviewed the study before use.

The subject must be informed of the new information in a timely manner and communication of this information documented in the subject’s medical notes.

The subject must be given ample time to consider their continued involvement and to ask questions before being asked to sign the revised Consent Form.

A copy of the revised documentation must be provided to the subject, and placed in the medical notes and Investigator Site File.

6. References and Bibliography

HRA/MRC: Principles of Informed Consent:
http://www.hra-decisiontools.org.uk/consent/principles.html

Health Research Authority
http://www.hra.nhs.uk/

ICH Good Clinical Practice Guidelines:

Declaration of Helsinki:
https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
Appendix 1: Information to be provided to potential trial subjects

According to ICH GCP (4.8.10) the discussion prior to a subject consenting to participation in a trial and the patient information sheet or any other written information relating to the trial should contain the following (unless otherwise approved by an Ethics Committee):

1. A statement that the trial involves research.
2. The purpose of the trial.
3. The trial treatment(s) and the possibility of random assignment to each treatment; diagrams may be useful.
4. The frequency of all trial procedures to be followed, including all invasive procedures.
5. The responsibilities of the subject.
6. The experimental aspects of the trial.
7. Any foreseeable risks or inconveniences for the trial subject.
8. The reasonably expected benefits, if any, should be explained. If there is no clinical benefit intended, the subject must be made aware of this.
9. Alternative treatments and procedure(s) that may be available and the potential benefits and risks.
10. The compensation and/or treatment available to the subject in the case of any injury relating to the trial.
11. Anticipated pro-rated payment, if any, to the subject for participating in the trial.
12. The anticipated out of pocket expenses, if any, to the patient for participating in the trial.
13. That the subject’s participation in the trial is completely voluntary and that the subject can withdraw or refuse to participate, or withdraw from the trial at any time without penalty or loss of benefits to which they would otherwise be entitled and without affecting their future care.
14. That authorised representatives from regulatory bodies, pharmaceutical company (or other commercial company, if appropriate to the study) will be given access to the subjects’ records for the purpose of verification of the trial procedures and data collected without violating the confidentiality of the subject. If applicable, that the subject’s General Practitioner will also be informed in writing of their participation in the study. By signing the informed consent form, the subject is authorising such access.
15. That records identifying the subject will be kept confidential and will not be made publicly available. If the results of the study are published, the subject’s identity will remain confidential.
16. That the subject /legal representative will be informed in a timely manner if any information becomes available that may be relevant to the subject’s willingness to continue to participate in the trial.
17. The person(s) to contact for further information regarding the trial (if possible record a 24hour phone number where the subject can receive advice out of office if required).

18. The foreseeable circumstances under which the subject’s participation in the trial may be terminated.

19. The expected duration of the subject’s participation in the trial.

20. The approximate number of patients involved in the trial.