Dorset HealthCare University NHS Foundation Trust

Standard Operating Procedure for Seeking Informed Consent

Objectives	The objective of this SOP is to explain local process for research staff seeking informed consent.
Scope	Applies to all research staff obtaining informed consent for research purposes.
Responsibility	It is the responsibility of all research staff to adhere to this SOP.
Related Document	RES SM 005 Site Staff Responsibilities RES SA 019 Adverse Event, Serious Adverse Event and Suspected Serious Adverse Reactions Reporting

1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to explain the local process by which the Dorset HealthCare University NHS Foundation Trust research staff seek informed consent from patients who wish to participate in research.

2 Introduction

Informed consent is the process by which a subject voluntarily confirms his or her willingness to participate in a particular study after having been informed of all aspects of the study that are relevant to their decision to participate and the documentation thereof.

ICH Good Clinical Practice guidelines also state: “The INVESTIGATOR or a PERSON DESIGNATED BY THE INVESTIGATOR, should fully inform the subject” and the subject must have “ample time and opportunity to inquire about details of the trial and to decide whether or not to participate” and the subject and the person conducting the informed consent discussion should sign and personally date the informed consent form.

The investigator/delegated responsible person must ensure that subjects have fully understood what they are consenting to.

This SOP describes the procedure for obtaining written informed consent from a potential study subject. This involves informing the subject by means of verbal explanation and written information.

3 Training

New users must read and understand this SOP before carrying out this procedure. Existing users must read and understand the Revisions Section.

Staff seeking consent must have a current GCP certificate.

4 Revisions

This is the second version of this SOP.

5 Procedure

5.1 Written informed consent must be obtained before any study-specific procedures are undertaken.

5.2 The investigator, or a suitably qualified person designated by the P.I. and agreed by the C.I. may obtain written consent from the subject.

The person to whom this responsibility is delegated must:

- only take consent if they feel confident and competent to do so, with a full understanding of the protocol and associated disease area;
- be suitably trained and qualified and have sufficient knowledge of the proposed investigation or treatment. They should have achieved level 4 of the NHS KSF core dimension 1 – Communication;
- understand the risks involved.

5.3 The names of the research personnel responsible for obtaining informed consent should be included on the Site Specific Information (SSI) form (question 12 on the IRAS SSI form).

5.4 Potential study patients will be identified and will be approached by the investigator/delegated responsible person or other member of the research team.

5.5 It is important that the investigator/delegated responsible person are fully familiar with the study protocol, patient information sheet and consent form prior to obtaining informed consent.

5.6 A description of the study will be given to the patient verbally using non-technical language and other resources (such as video or diagrams) as appropriate. The investigator (or other research professional designated by the investigator) should answer any questions the patient may ask, to the patient's satisfaction.

5.7 The patient should also be provided with a written patient information sheet and informed consent form, which will generally cover the following:

- That the trial includes research.
- The purpose of the trial.
- Details about the treatment under investigation. If there is a placebo arm to the study, this must be carefully explained. The probability of random assignment to each treatment.
- The design of the trial, for example 'crossover'. A diagram may be helpful.
- Details of, number and frequency of all trial procedures to be followed, noting all invasive procedures.
- The responsibilities of the subject if he/she participates.
- The aspects of the trial that are experimental.
- The reasonably foreseeable risks or inconveniences to the patient.
- The reasonably expected benefits. If no clinical benefit is intended, the subject must be made aware of this.
- The alternative procedures or treatments that may be available to the patient and the potential benefits and risks of such alternatives.
- The availability of compensation and treatment if needed in the event of a trial-related injury.
- The anticipated pro-rated payment, if any, to the patient for participating in the trial.

- The anticipated out of pocket expenses, if any, to the patient for participating in the study.
- That the patient's participation in the trial is voluntary and that the patient may refuse to participate, or withdraw from the trial at any time without penalty or loss of benefits.
- That the authorised representatives from regulatory bodies, the pharmaceutical company (or other commercial company if appropriate to the study) or the Research Ethics Committee (as appropriate) will be given access to the patient's records for the purpose of verification of the trial procedures and data collected, without violating the confidentiality of the patient' this may include transmitting the coded subject's data outside of the EU. By signing the informed consent form, the patient is authorising such access. If the study is within the UK and involves the Office of Population Census and Surveys this confidential procedure will be explained to the patient. Account must be taken of the EU Data Protection Act legislation.
- That the records identifying the patient will be kept confidential and will not be made publicly available. If the results of the study are published, the patient's identity will remain confidential.
- That the patient (or their legally acceptable representative) will be informed in a timely manner if any information becomes available that may be relevant to the patient's willingness to continue to participate in the trial.
- The person(s) to contact for further information regarding the trial and a 24 hour telephone number in the event of an adverse event.
- The foreseeable circumstances under which the patient's participation in the trial may be terminated.
- The expected duration of the patient's participation in the trial.
- The approximate number of patients involved in the trial.

5.8 The written information sheet and informed consent form used must have received Research Ethics Committee approval, be identifiable by a version date and/or number and be printed on local headed paper.

5.9 The patient should be given adequate time to read and consider the information given as appropriate. Ideally, patients should have a period of at least 24 hours after receiving this information for their consideration.

5.10 Once the patient has agreed to participate in the study, the informed consent form should be signed and personally dated by:

- The patient
- The investigator / delegated responsible person

Each person's name should be clearly printed alongside his or her signature. It is especially important that each person dates his or her own signature only.

5.11 Before the investigator/delegated responsible person obtains the written informed consent they have the responsibility to ensure that the patient comprehends what it entails.

5.12 The original signed informed consent form will be kept with the patient information sheet in the study file. The patient will be given a copy of the written information and the signed consent form to keep and a copy should be placed in the patient's medical record. The informed consent discussion should also be documented in the patient's medical record.

5.13 Procedure when consenting Incapacitated Adults:

The main points are:

- The subject should receive information according to their capacity to understand it.
- The explicit wish of the subject to refuse participation is considered by the investigator.
- There are grounds for expecting that administering the medicinal product to be tested will produce a benefit to the subject.

5.14 Procedure when consenting Minors:

The main points are:

- The subject should receive information according to their capacity to understand it.
- This information should be given to the child by staff who have experience of working with minors.
- The explicit wish of the subject to refuse participation is considered by the investigator.
- The clinical trial relates directly to a clinical condition from which the minor suffers or is of such a nature that it can only be carried out on minors.

In both cases of vulnerable subject their legal representative (the person with parental responsibilities in the case of a child) must:

- Be given relevant information about the trial;
- Give informed consent on behalf of the subject (the subject gives their consent if capable);
- Must represent the subject's presumed will
- Has the right to withdraw the subject.

6 Appendices

There are no appendices to this SOP.

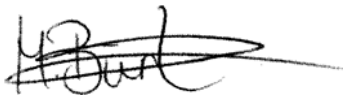
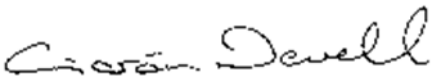
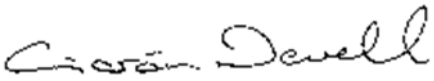
7 Responsibilities

It is the responsibility of the Principal Investigator to receive informed consent or delegate this duty to a suitably qualified person.

8 Review

This SOP should be reviewed every two years unless new guidance or legislation dictates a review any sooner.

Date reviewed: 12/04/19 Date of next review: 12/04/21

Written By	Signature	Date
Hazel Burt		12/04/19
Reviewed By	Signature	Date
Dr Ciarán Newell		12/04/19
Authorised By	Signature	Date
Dr Ciarán Newell		12/04/19