

Standard Operating Procedure

Title: INFORMED CONSENT		
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1. BACKGROUND

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. It is unacceptable to enrol a subject in a research study without first informing them and obtaining their explicit consent.

The Declaration of Helsinki states that: *“In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the **physician** should then obtain the subject’s freely given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.”*

ICH Good Clinical Practice guidelines also states that: *“The Investigator or a person designated by the Investigator, should fully inform the subject”,* that the subject should have *“ample time and opportunity to inquire about details of the trial and to decide whether or not to participate.”* The subject and the person conducting the informed consent discussion should sign and personally date the informed consent form.

The investigator should ensure that subjects have fully understood what they are consenting to. Any other research personnel involved in giving information during the informed consent procedure should also sign and personally date the informed consent form.

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2. PURPOSE

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

3. OTHER RELATED PROCEDURES

SOP 002 Definition of Responsibilities

4. WHEN

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

5. WHO

The investigator or other designated members of the research team can give the verbal explanation of the study.

The investigator (or a **medically qualified** co-investigator) is the only individual who may obtain informed consent from subjects in clinical trials involving Investigational Medicinal Products (CTIMPs) or Medical Devices authorised by the MHRA^a.

If the study that involves **no** clinical interventions, **and** a Research Ethics Committee has granted approval for a *non-medically qualified* Chief (or locally, Principal) Investigator, informed consent may be taken by that non-medically qualified person.

6. HOW

Potential study patients will be identified and will be approached by either the investigator or other member of the research team.

It is important that the Investigator is fully familiar with the study protocol, patient information sheet and consent form prior to obtaining informed consent.

A description of the study will be given to the patient verbally using non-technical language and if necessary using diagrams. This discussion is important and the Investigator (or other medically qualified person designated by the Investigator) **must** answer any questions the patient may ask, to the patient's satisfaction.

^a Medicines and Healthcare products Regulatory Authority (UK Competent Authority)

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The informed consent discussion should cover the points given below. The patient **must** also be provided with a written patient information sheet and informed consent form, which must also contain explanations of the following:

- That the study involves research
- The purpose of the study
- 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 and the consequences of placebo 'treatment' must be explained; as must the fact that Investigator will not (or may not) know if placebo is being prescribed depending upon the nature of 'blinding'.
- The design of the study. A diagram may be helpful.
- Details of, including the number and frequency of all study procedures to be followed, noting all invasive procedures.
- The responsibilities of the subject if he or she chooses to participate.
- The aspects of the study 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. [Note: Societal benefit (eg: future patients) is a valid reason for research and will receive ethical approval in most instances. However, it should be made clear to participants that there may no direct benefit to them]
- 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 study-related injury
- The anticipated pro-rated payment, if any, to the patient for participating in the study
- The anticipated out of pocket expenses, if any, to the patient for participating in the study
- That the patient's participation in the study is voluntary and that the patient may refuse to participate, or withdraw from the study at any time without penalty or loss of benefits.

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- That authorised representatives from regulatory bodies, the pharmaceutical company (or other commercial company, if appropriate to the study), Trust regulatory bodies, or the Research Ethics Committee (as appropriate) will be given access to the patients' records. This is for the purpose of verification of the study procedures and data collected, and will be carried out without violating the confidentiality of the patient. 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.
- That 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 study.
- The person(s) to contact for further information regarding the study (with a 24 hour telephone number) in the event of an adverse event
- The foreseeable circumstances under which the patient's participation in the study may be terminated
- The expected duration of the patient's participation in the study
- The approximate number of patients involved in the study

The written information sheet and informed consent form used **must** be that which received approval from the Research Ethics Committee and be identifiable by a date and version number; it **must** and be printed on WHNT headed paper.

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.

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

- The patient
- The medically qualified Investigator

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.

Before the investigator obtains the written informed consent they have the responsibility to ensure that the patient comprehends what it entails.

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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. A copy ***must be placed in the patient's medical record.***

The informed consent discussion should also be documented in the patient's medical record.