	Title : Procedure for obtaining written informed consent.	Author: G. Cockerill	Date: 2/Oct/2012
	No: SOP_R12	New Author: P. Madhou	Date: 1/Sept/2024
	Version: 6		Review Date March 2026




SOP_R12: PROCEDURE FOR OBTAINING WRITTEN INFORMED CONSENT.

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Out of date documents must not be relied upon and should be destroyed.

6	Sept 2024	City merge, Review & format	AS/PM	HTLRG
5	Sept 2023	New DI, update contacts & formatting	AS	HTLRG
5	Sept 2022	New DI, Add PD & Review	AS	HTLRG
4	August 2020	Review (Links & References updated)	AS/PL	HTLR
3	March 2018	Reviewed & Amended (New Author)	AS	PL
3	July 2017	Reviewed and PD contact details updated	AS	PL
3	July 2017	Reference to HTA codes updated	PL	HTLRG
3	July 2017	Reviewed and PD contact details	PL	HTLRG
2	5/12/16	Update contact list	AS	PL
2	10/10/16	DI change details	AS	MF
2	17/03/16	Issued for use	GC	HTLRG
1	30/10/12	Issued for use	GC	HTLRG
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Rev	Date	Amendment	Approved by	Authorised by

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1. Background

Patients have a fundamental legal and ethical right to determine what happens to their bodies. Valid consent is essential in healthcare and research, reflecting both legal obligations and the common courtesy owed by health professionals to patients. Informed consent in a research context is the process by which a competent subject voluntarily confirms their willingness to participate in a study, after comprehending all relevant aspects. It involves an exchange of information, discussion, and the subject's verbal and written consent.

Written consent is mandatory for research and is documented through:

- **Patient Information Sheet (PIS):** Describes the research in layman's terms. SOP :
- **Consent Form:** Documents that informed consent has been taken, when, and by whom.

The consent process must be documented in the subject's medical records. Valid consent requires voluntariness, capacity, and appropriate information.

Written consent merely serves as evidence of consent. A signature on a form will not make the consent valid if the elements of capacity, voluntariness and appropriate information have not been satisfied.

2. Purpose

This SOP describes the process of obtaining written informed consent from a study subject. This involves informing the subject by means of a verbal explanation and written patient information. Guidelines for the consent of more vulnerable subjects can be found in the appendices

The SOP must be read and understood before obtaining consent and referenced if any doubt arises during the process.


For further information, refer to the [NRES website](#).

3. Procedure

3.1 Who?

The Principal Investigator (PI) is responsible for obtaining valid consent. The GMC emphasises providing comprehensive information to potential subjects and allowing sufficient time for decision-making. ICH Good Clinical Practice (GCP) guidelines state that the investigator or a designated person should fully inform the subject. Delegation of informed consent should be decided on a trial-by-trial basis, considering local circumstances and ICH GCP guidelines.

ICH Good Clinical Practice Guidelines [ICH Official web site : ICH](#)

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3.2 When?

Informed consent must be obtained before any research-related procedures. Subjects should be given adequate time, usually at least 24 hours, to review the information sheet and discuss it with family or friends before agreeing to participate. The minimum decision-making time is determined during NHS Ethics approval.

3.3 How?


Informing the Subject:

Informing the subject

1. Patient information should be provided to potential study subjects in both a verbal and written form. The person taking informed consent should provide the subject with a written information sheet, on hospital headed paper, detailing the study.
2. Obtaining consent for research should generally be a two stage process. The first being the provision of information, discussion of options and initial (oral) decision, and the second being confirmation that the patient still wants to go ahead. Patients should be given adequate time to decide whether or not to participate before being asked to sign the consent form.
3. ICH GCP (4.8.10) describes what should be explained to the research subject during the discussion prior to them consenting to participate in a trial and in the patient information sheet (or any other written information relating to the trial). You should check that the verbal discussion is consistent with the information sheet provided and includes the elements listed in Appendix A.
4. Since the consent form specifies what precisely the patient is giving permission for, it should be provided along with the information sheet at the initial discussion.

Taking Informed Consent

5. When the person taking informed consent is satisfied that the subject has been fully informed and understands what study participation entails the consent form should be signed and personally dated by the subject and by the person who conducted the informed consent discussion.
6. The principal investigator retains overall responsibility for gaining a subject's informed consent. However, where an authorised person has been delegated to take consent and that

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person is named on the delegation log, the Principal Investigator does not need to countersign the consent form. All persons taking consent MUST be named on the delegation log in advance of consent being taken.

7. Only the latest consent form (and matching patient information sheet) approved by the main research ethics committee should be used. Ensure that the form is completed appropriately – where the patient is asked to initial against a series of statements, ensure that these are initialled and not merely ticked.

8. There should be three copies of the signed and dated consent form. The original should be filed in the patient's hospital notes, while a copy should be given to the patient for their records and a third copy filed in the study file.

9. The process of obtaining informed consent should be documented in the patient's medical records, detailing the name of the study and the date on which consent was obtained. The entry should be dated and signed by the person authorised and responsible for conducting and obtaining the patient's informed consent. A statement confirming that the patient was eligible for the study, according to the protocol, should be included.

10. Subjects should get copies of all relevant, updated, and new information regarding the study throughout their participation (for example, in the event of amendments to the trial methodology)

11. The subject's General Practitioner should be informed about their participation in the study and should receive appropriate information regarding the study.


4. Other Related Procedures

- Delegation of Responsibilities
- Study Files and Filing

5. References and Further Reading

- [Code A: Guiding principles]
- [Codes of Practice | Human Tissue Authority \(hta.gov.uk\)](https://hta.gov.uk)
- ICH Harmonised Tripartite Guideline for Good Clinical Practice (1996)
- Declaration of Helsinki (2000 Version)
- Research Governance Framework for Health and Social Care (2nd Edition April 2005)
- The Medicines for Human Use (Clinical Trials) Regulations 2004
- The Mental Capacity Act 2005


6. Appendices

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Appendix A - Essential information to be provided within the informed consent discussion.

- A statement that the trial involves research.
- The purpose of the trial.
- The trial treatment(s) and the possibility of random assignment to each treatment.
- The trial procedures to be followed, including all invasive procedures.
- The subject's responsibilities.
- The experimental aspects of the trial.
- Any foreseeable risks or inconveniences for the trial subject.
- The reasonably expected benefits. If there is no clinical benefit intended, the subject must be made aware of this.
- Alternative treatments and procedure(s) that may be available and the potential benefits and risks.
- The compensation and/or treatment available to the subject in the case of any injury relating to the trial.
- Anticipated pro-rated payment, if any, to the subject for participating in the trial.
- The anticipated out of pocket expenses, if any, to the patient for participating in the trial.
- That the subject's participation in the trial is completely voluntary and that the subject can withdraw or refuse to participate, at any time, without penalty or loss of benefits to which they would otherwise be entitled and without affecting their future care.
- That authorised representatives from regulatory bodies, pharmaceutical company (or other commercial company, if appropriate to the study), sponsor or the Research Ethics Committee (as appropriate) will be given access to the subject's records for the purpose of verification of the trial procedures and data collected, without violating the confidentiality of the subject. 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.
- 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.
- 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.
- 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).
- The foreseeable circumstances under which the subject's participation in the trial may be terminated.
- The expected duration of the subject's participation in the trial.
- The approximate number of patients involved in the trial.


Appendix B: Guidance on the Consent of Minors

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- It is essential that the clinical study relates directly to a clinical condition from which the minor suffers or is of such a nature that the study can only be carried out on minors.
- It is important to show that there will be some benefit for the group of patients involved in the study and that the clinical study is necessary to validate data obtained in other clinical studies involving persons able to give informed consent or by other research methods.
- The clinical study needs to be designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and the minor's stage of development. Continuous monitoring throughout the study of such risks and/or distress must take place. The interests of the minor must always prevail over the interest of science.
- The person with parental responsibility for the minor and the minor themselves must be made aware that they can withdraw from the study at any time without any detriment to future care.
- No incentives or financial inducements must be given except for compensation in the event of injury or loss.


Appendix C: Guidance on Consenting Patients with Communication Difficulties

- The legal position is that adults must be presumed capable of taking decisions unless the opposite has been demonstrated. This applies just as much to people with learning disabilities as to any other adult.
- Where there are comprehension or communication difficulties then subjects must be given all appropriate help to enable them to make their own decisions e.g. using visual aids, sign language etc.
- If a decision is taken to enroll subjects with communication problems or comprehension difficulties, then investigators must have a clear plan about how these matters will be managed and documented in the consent process.
- Where there are communication difficulties, a relative or an independent patient's advocate should be involved in the consent process. The latter's role is to help the prospective subject express their views. Therefore, two types of information sheet may
- be required: one for the relative and one for the patient. The latter should be designed to overcome or minimize some of the communication problems, for example, a pictorial information sheet for the research subject.
- Sufficient time must be allowed for the person seeking consent to explain and discuss the proposal with the subject and the relative or advocate, and for the relative or advocate to discuss with the prospective subject.
- For the consent to be valid the research subject must always be able to communicate their decision. If the person is unable to sign or to mark the consent form so as to indicate his/her consent, then consent may be given orally in the presence of at least one witness, usually a relative or patient.
 - advocate. The role of the relative or advocate in the consent process, for example, acting as a witness or explaining the trial to the subject, must be documented in the medical records. Consent could also be recorded to provide a complete record with a copy of the tape for the participant.
- All hospital staff that provide information and request consent from patients with communication problems or comprehension difficulties must be appropriately trained and experienced with such patients.

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Appendix D: Guidance on the Consent of Incapacitated Adults

- Legally, adults must be assumed to be capable of taking decisions unless the opposite has been demonstrated for a particular decision.
- Where doubt exists, the Principal Investigator or another experienced and independent clinician should formally assess the capacity of the individual to make an informed decision about participation in a research project. This assessment and the conclusions should be recorded in the medical records.
- A patient is deemed to lack legal capacity to consent or refuse only when they cannot be helped to reach their own decision with memory aids or sign language for example.
- The study must relate directly to a life threatening or debilitating clinical condition from which the subject suffers and that there are grounds for expecting that the study procedure/intervention to be tested in the study will produce a benefit to the subject, outweighing the risks or producing no risks at all.
- The clinical study must be essential to validate data obtained in other clinical studies involving persons able to give informed consent or by other research methods.
- The clinical study needs to be designed to minimise pain, discomfort, fear, and any other foreseeable risk in relation to the disease and the cognitive abilities of the subject and continuous monitoring throughout the study of such risks and/or distress must take place. The interests of the subject must always prevail over the interest of science.
- No one can currently consent to research on behalf of an incapacitated adult. The research investigator must however identify a legal representative who can be consulted about the involvement of the subject in the study.
- If no suitable personal legal representative (e.g. relative) is available then a professional legal representative may be approached (e.g. doctor primarily responsible for medical treatment or a person nominated by the trust). However, this representative must not be connected with the conduct of the trial in any way.
- Where a legal representative has been appointed, they must have an interview with a member of the study team to understand the objectives, risks, inconveniences/discomforts and associated conditions for the study and be provided with a contact number for the study team should they wish to ask further questions about the study. The legal representative must be informed of their right to withdraw the subject at any time resulting in no detriment to care or treatment for the subject.
- Subjects should not be enrolled into the trial if it is contrary to a formal advance decision or any other form of statement made in advance by the subject whilst competent. This does not have to be in writing and an investigator should take reasonable steps to find out if there are any advance wishes by consulting relatives. Any patient's 'dissent' must always be respected throughout, especially in non-therapeutic research, even if they do not have the legal capacity to refuse.

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- The subject must also be given information regarding the study according to their level of understanding. For those subjects able to form an opinion based on the information provided, their wish to participate must be respected by the person taking consent.
- The role of the patient's representative, their relationship to the patient and the response of the subject should be documented. The opinion of the patient's representative about enrolment should be formally documented and a written and signed statement obtained.
- No incentives or financial rewards must be used to influence a subject to participate (or the subject's legal representative to agree to participation on their behalf) in a study other than provision for compensation in the event of loss or injury.

7. Amendment of SOPs

If any modification is identified that could improve this SOP, it should be reported to the Person Designated (PD) for review and potential implementation.

This SOP ensures that all research personnel understand and follow the proper procedures for obtaining informed consent, safeguarding both the rights of the patient and the integrity of the research process.

15. Contacts DIs and PDs

Research Licence	DI	Dr Priya Madhou	Ext 1603	pmadhou@sgul.ac.uk
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Anatomy Licence	DI	Miss Georga Longhurst	Ex 5208	glonghur@sgul.ac.uk
	PD	Mr Paul Carter	Ext 5228	pcarter@sgul.ac.uk
	PD	PATHOLOGY MUSEUM Dr Carol Shiels	Ext 0729	cshiels@sgul.ac.uk