Taking Informed Consent

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Version Number: 2.0
Effective Date: 01.08.11
Review Date: 31.07.13

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<tr>
<th>Version Number</th>
<th>Edited by</th>
<th>Effective Date</th>
<th>Details of Changes</th>
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</thead>
<tbody>
<tr>
<td>1.0</td>
<td>JG/GB</td>
<td>01.08.10</td>
<td>First version</td>
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<tr>
<td>2.0</td>
<td>GB</td>
<td>01.08.11</td>
<td>Reviewed</td>
</tr>
</tbody>
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1. BACKGROUND

Patients have a fundamental legal and ethical right to determine what happens to their own bodies. Valid consent to treatment is therefore absolutely central in all forms of healthcare. Seeking consent is also a matter of common courtesy between health professionals and patients.

Informed consent in the context of a research study, is the process by which a competent subject voluntarily confirms his or her willingness to participate in a particular study and the associated documentation, after having been informed of and having comprehended all aspects of the study that are relevant to their decision to participate. Informed consent is a process of information exchange, which involves the giving of information, the discussion and clarification of the information and taking the subject’s verbal and written consent.

It is morally and professionally unacceptable to perform any research related procedure on someone without first obtaining their informed consent. Written evidence of the consent for research is explicitly required by ICH GCP.

Written documentation consists of two elements:

- The patient information sheet (PIS). Describes the research in laymans terms.
• The consent form. Documents that informed consent has been taken, when, and by whom.

The process of obtaining informed consent should be documented in the subject’s medical records. For consent to be valid, it must be given voluntarily by an appropriately informed person (the patient or someone with parental responsibility for a patient under the age of 18) who has the capacity to consent to the intervention in question.

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.

It is important that this SOP is read and understood before study personnel start taking consent, but it should also be referred to if any doubt arises regarding the process of informed consent during the study. You should refer to the NRES website www.nres.npsa.nhs.uk for further information.

3. PROCEDURE

3.1 Who?

It is the responsibility of the Principal investigator to obtain valid consent from research subjects. The GMC states that “particular care” should be taken to ensure that possible research subjects have the fullest possible information about the proposed study and sufficient time to absorb it.

ICH Good Clinical Practice guidelines state “The investigator, or, a person designated by the Investigator should fully inform the subject” (ICH GCP 4.8.5) and the written informed consent form should be signed and dated by the “person who conducted the informed consent discussion”. 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.

3.2 When?

Informed consent must be obtained prior to any research related procedures being performed. Subjects should be given adequate time, usually at least 24 hours, to read the information sheet and to discuss with any family and friends (if applicable), prior to agreeing to participate. The minimum time given for the
patient to make a decision will have been agreed as part of the NHS Ethics approval process.

3.3 How?

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 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

ICH Harmonised Tripartite Guideline for Good Clinical Practice (1996)

Declaration of Helsinki (2000 Version)


The Medicines for Human Use (Clinical Trials) Regulations 2004 Statutory Instrument 2006/1031, implemented on the 1st May 2004 as amended

The Mental Capacity Act 2005

Much of the text in this SOP has been adapted from:


Obtaining Informed Consent in Clinical Trials of Investigational Medicinal Products. North Yorkshire R&D Alliance v1.0 08.04.2008

6. APPENDICES
Appendix A – Essential information to be included in the informed consent discussion
Appendix B – Guidance on the Consent of Minors
Appendix C - Guidance on Consent of Adults with Communication Difficulties
Appendix D – Guidance on the Consent of Incapacitated Adults
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

Consent of minors

- 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.

- A full explanation of the study including the objectives, risks, inconveniences and all the conditions associated with the study must be given to the person with parental responsibility for the minor in order that they provide consent for the minor to participate in the study. If they are unable to be contacted due to the emergency nature of the treatment provided as part of the study, then a legal representative for the minor must have had an interview with the CI/PI or another member of the study team in which they have been given the opportunity to understand the objectives, risks and inconveniences and be able to provide consent to the minor taking part. A contact number for the research team must be given in order for them to obtain further information regarding the study should they wish to do so.

- It is important for the minor to be given information regarding the study according to his/her level of understanding (from staff that have experience in dealing with minors) and the person taking consent must respect their wishes. In cases where the child has been involved and are judged competent to give consent then they should also sign the form. It is also good practise to document the child’s view where they are not judged competent to give consent.

- 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 enrol 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.
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.

• 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.