Title: Informed consent procedures in the NIHR/Wellcome Trust Imperial CRF (ICRF)

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Author(s):	David Lewis Head of Clinical Studies
Contact Details:	david.lewis@imperial.nhs.uk
Reviewer(s):	Marion Watson QA Manager, Susanne Fagerbrink Lead Nurse
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Document version numbering

Version	Date	Updated by	Reason for change
1	May 2011	S Othman	New SOP for the SJMC
2	Aug 2013 amended Dec 2014	T Mohammad M Watson	Extended procedures; change of CRF name; minor amendments at Quality, Health and Safety Review
3	Aug 2016	M Watson S Fagerbrink	Biennial review, removal of appendix, simplified wording, inclusion of option for non-medics to take consent

1.0 BACKGROUND

"Informed consent is a process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written signed and dated Informed Consent Form." ICH -GCP (1996), 1.28

Initial informed consent is a three step process which involve:

- Giving information (written and verbal)
- Clarifying the information and answering questions
- Recording written consent.

Informed consent is a continuing process which requires assurance throughout the study.

2.0 PURPOSE

This SOP describes the process for obtaining informed consent from study participants at the ICRF. It outlines procedures for adult subjects with and without capacity.

3.0 SCOPE

This SOP applies to all staff and researchers working in ICRF. Currently the ICRF does not carry out research on minors.

4.0 GLOSSARY

CI	Chief Investigator
Consultee	Gives opinion on whether someone would agree to take part in a given study if they had mental capacity (non CTIMPs)
CTIMP	Clinical Trial of an Investigational Medicinal Product (drug)
ICF	Informed Consent Form
ICH-GCP	International Conference on Harmonisation of Good Clinical Practice
ICHNT	Imperial College Healthcare NHS Trust
ICRF	NIHR / Wellcome Trust Imperial Clinical Research Facility
iSF	Investigator Site File
iTMF	Investigator Trial Master File
Legal Representative	Gives consent on behalf of a participant (CTIMPs only)
PI	Principal Investigator
PIS	Participant Information Sheet
REC	Research Ethics Committee

5.0 RESPONSIBILITIES

5.1 Responsibility for obtaining consent

ICH-GCP states that '*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 (ICF) 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(s) of the research team should be considered on a study-by-study basis.

Anyone accepting responsibility for the informed consent process must ensure:

- They are prepared to take on this additional responsibility and feel confident to seek informed consent in line with their professional organisational guidelines.
- They have a full understanding of the study, potential risks/benefits and the associated disease area.
- They should be qualified by experience and/or should have received appropriate training for this study. All training must be documented. A copy of signed and dated CVs must be filed in the iTMF/iSF.
- The process is carried out as approved by the relevant REC.
- Delegation of responsibility to take consent is documented on the Study Delegation Log.
- An effective line of communication is maintained to the CI/PI or delegate who is the person ultimately responsible for the participant's care.

A member of the research team will provide verbal information, answer questions and witness the participant signing the consent form. They will then sign the consent form and record consent in the healthcare records.

5.2 The research team

The research team should assist the volunteer as much as they need to come to a decision about taking part. They should refer any problems or queries that they are not able to deal with to the CI/PI or delegate as appropriate.

All researchers are responsible for ensuring continuing consent (Section 6.6)

5.3 Governance

It is the responsibility of the ICRF Lead Nurse to ensure that nurses and health care staff are trained to follow this SOP.

It is the responsibility of all ICRF staff and researchers to follow the procedure and complete/file all documentation appropriately.

It is the responsibility of all CIs/PIs to ensure their team are trained to follow this SOP.

It is the responsibility of the ICRF QA Manager to ensure this SOP is reviewed and updated as required.

6.0 PROCEDURES

6.1 When is consent required

All research participants must have given informed consent before any aspect of the study starts.

Pre-screening of healthcare records or clinic lists in order to identify potential participants may be carried out by healthcare practitioners involved in the care of those patients without prior consent provided this has been detailed on the REC application and received a favourable opinion.

The ICRF has a database of healthy volunteers. Consent is only obtained for their details to be on the database and to be accessed by ICRF researchers. Study-specific consent is required when these volunteers are recruited to any study.

6.2 Provision of information

The participant must be given an information sheet (PIS) about the study and have the opportunity to read and understand it before giving consent. These processes will be covered

in the study protocol and REC application and any amendments. All documents including the PIS and ICF must have a favourable opinion from a REC.

6.3 Informed consent of adults with capacity

All potential participants should be given information about the study in accordance with the procedures and timings detailed in the REC application. Usually the PIS will be given in a clinic or sent via post/e-mail a minimum of 24hrs before consenting.

6.3.1 The dignity of the potential participant should be considered and consent discussions should take place in a private area.

6.3.2 A verbal explanation of the study must be given to the potential participant. If necessary, diagrams should be used to explain the study. Time must be allowed for questions throughout the discussion and questions answered adequately.

6.3.3 When describing the study the person seeking consent should explain all elements of the PIS. Local detail may be needed such as how to gain access to the ICRF, how payments will be made and how long they will take, information on temporary accommodation etc.

6.3.4 They should explain that giving informed consent does not always mean the volunteer will be enrolled into the study if it is discovered they do not meet the inclusion/exclusion criteria e.g. a study specific diagnostic test.

6.3.5 Volunteers must not be coerced to participate, and must be reassured that refusing to enter the study will not affect their care.

6.3.6 Once the volunteers have had time to read the PIS and have had any questions answered satisfactorily, they should be asked to sign the study-specific ICF. In some cases there may be more than one consent form e.g. if there is an optional DNA test.

6.3.7 The ICF(s) must be personally signed and dated by the participant and by the person seeking consent. Each should clearly print their name by their signature. Fountain pens or other inks which can easily smudge or run must not be used; black biro is the preferred option. Green does not photocopy well and should be avoided.

6.3.8 The signed original ICF and a copy of the PIS must be stored in the iTMF/iSF. A copy of each should be given to the volunteer and a copy put in the appropriate section of the healthcare record The study IDand date of consent should be recorded in the clinical history.

6.3.9 If there are separate consent forms for clinical investigations or treatment the originals of these should be filed in the healthcare records.

6.3.10 All participants must be provided with contact details for further information about the study. Once their participation starts this will either be the ICRF out of hours phone, or a number agreed by the ICRF Protocol Review Board (see SOP ICRF-OR22 ICRF Out of Hours Phone).

6.4 Consent from participants with limited understanding of English.

6.4.1 It is essential that the person taking consent is confident that the participant is fully informed. If the participant's first language is not English an interpreter must be provided by the research team.

6.4.2 The interpreter may be a member of the research team, the ICRF staff or any person independent from the study but with sufficient understanding to be able to explain essential information. Medical knowledge may be necessary. An interpreter may be

available from the ICHNT service but note that for research this may incur a cost.

6.4.3 Use of family members as translators for research consent (as distinct from consent for medical care) is strongly discouraged as it is impossible to be confident of correct translation, lack of coercion or that all the volunteer's questions have been answered.

6.5 Informed consent of incapacitated adults

6.5.1 **IMPORTANT** Researchers must be aware of the possibility of a participant losing mental capacity during the study either through deteriorating health or through accident or injury. In such cases the CI/PI must:

- Check the REC application form for the declaration of intent in such circumstances.
- If it was agreed such a participant would be withdrawn this must be enacted as soon as possible whilst ensuring that the health of the participant is not compromised e.g. a drug may require gradual dose reduction. If it was agreed such a participant could continue, re-consent will be required involving their legal representative or consultee as in 6.5.3 below.

6.5.2 When seeking consent from an adult who is unable to provide informed consent for themselves it is important that the Investigator is trained in the relevant legislation; currently Schedule 1 Parts 1 and 3 of the Medicines for Human Use (Clinical Trials) Regulations 2004 for CTIMPs and the Mental Capacity Act 2005 for all other clinical research.

6.5.3 Studies on participants lacking capacity from the start of their involvement must:

- Relate directly to a life threatening or debilitating clinical condition from which the participant suffers, and it is expected that the study will produce a benefit to the participant. This benefit should outweigh the risks or there should be no risks at all.
- Where relevant, be essential to validate data obtained in other studies involving persons able to give informed consent, or by other research methods.
- Not permit incentives or financial rewards to be used to influence a participant or their legal representative/consultee, other than provision for compensation in the event of loss or injury.

6.5.4 The researchers must ensure that:

- They minimise pain, discomfort, fear and any other foreseeable risks to the subject. Risks and/or distress must be monitored throughout the study. The interests of the subject must always prevail over the interest of science.
- The participant's legal representative (CTIMPs) or consultee (non-CTIMPs) must have the objectives, risks, inconveniences/discomforts and associated conditions for the study explained to them. A contact number should be provided in case they wish to ask further questions. A legal representative must be informed of their right to withdraw the participant at any time resulting in no detriment to care or treatment for the subject.
- The participant must be given information about 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, or not, must be respected.

6.6 Ensuring valid informed consent at all study visits

6.6.1 The consent process does not end once the ICF has been signed. The practice of giving information about the study to participants should be on-going throughout the study.

6.6.2 Nurses and researchers should ensure that a properly completed ICF is available for all study related visits. They should confirm verbally that the participant is happy to continue and document this in the healthcare records.

6.7 Continuing consent and re-consent after amendments

6.7.1 On-going consent is particularly important if the protocol is amended or if important new information becomes available that may be relevant to the participant's willingness to continue taking part in the study. It may be necessary to re-consent the participant on an amended consent form.

6.7.2 Any amended PIS or ICF must be approved before use unless it forms part of an urgent safety measure notification. In such cases amended documentation may be issued and approval applied for as soon as possible, see SOP ICRF-OR10 Amendments.

6.8 Withdrawal of consent or dis-continuation

6.8.1 The participant may withdraw consent at any time without giving a reason.

6.8.2 The CI or PI may withdraw the patient if:

- They consider it is not in the participant's interest to continue. Information on such circumstances may be detailed in the study protocol e.g. Serious Adverse Events.
- Screening tests indicate inclusion/exclusion criteria have not been met. They should inform the participant whether or not they can be rescreened at a future date, what needs to change (e.g. discontinuing an excluded concomitant medication) and how long they must wait.
- Confirmation of suitability is not received from the participant's GP where this is required by the REC and/or the study protocol. Note: In most studies the researchers are only required to inform the GPs of their patient's participation.
- At any time if it is determined the participant should not have been included (protocol deviation).

7.0 Related Documents and References:

- ICH (1996) Guidelines for Good Clinical Practice – ICH Harmonised Tripartite Agreement http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html
- Declaration of Helsinki http://www.wma.net/en/20activities/10ethics/10helsinki/index.html
- MRC Research in emergency settings involving adults who cannot consent http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC004446
- Mental Capacity Act 2005 http://www.legislation.gov.uk/ukpga/2005/9/contents
- UK Medicines for Human Use (Clinical Trials) Regulations 2004 http://www.opsi.gov.uk/si/si2004/20041031.htm
- The Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006 http://www.uklaws.org/statutory/instruments_36/doc36129.htm