

University of Hertfordshire

INFORMED CONSENT

Clinical Trials Support Network (CTSN)

Standard Operating Procedure for Obtaining and Documenting Informed Consent in Research at The University of Hertfordshire

SOP Number : gSOP-04-01	Effective Date: 26 th April 2018
Version Number: v1.0	Review Date: 3 years(or as required)

1.0 BACKGROUND

This is a University of Hertfordshire standard operating procedure. University of Hertfordshire (UH) acknowledges West Hertfordshire Hospitals NHS Trust (WHHT) Research & Development (R&D) which has allowed UH to use the SOPs developed by WHHT where possible, modified for local implementation.

This document sets out the procedures to be followed by all UH staff who consent participants into research studies. Where there are potential conflicts between different collaborating organisations' SOPs, project level working instructions should be developed, to determine precedence.

It aims to provide clear guidance on the legal requirements and the procedures of taking informed consent when recruiting participants to research studies carried out in UH sponsored/co-sponsored studies.

The Sponsor shall ensure a valid informed consent was obtained prior to participants participating in research to meet ethical and regulatory requirements. Prior to trial initiation, for studies involving Trust participants the Sponsor should ensure that the study has received R&D confirmation from the collaborating hospital trust/s.

2.0 PURPOSE

Informed consent is a process by which a trial participant voluntarily confirms his or her willingness to participate in a research study after being duly informed of all aspects of the trial including the risks and benefits to the participant, alternative options, peripheral and altruistic nature of the research. The

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process should be carried out in stages, allowing sufficient time for the participant to understand oral and written information (e.g. Participant Information Sheet (PIS) and to clarify any arising queries. The participants must be informed that they are free to withdraw at any point in the trial after consenting if they wish to do so.

Informed consent is at the heart of ethical research. Most studies involving individuals must have appropriate arrangements for obtaining consent, and the ethics review process pays particular attention to those arrangements.

Freely given informed consent should be obtained from every participant prior to clinical trial participation.

The principles of Good Clinical Practice (GCP) state that in obtaining and documenting informed consent, investigators should comply with the applicable regulatory requirement(s) and adhere to GCP. Sponsor/PI shall ensure before starting a trial to obtain a written approval/favourable opinion from the ethics committee for the written informed consent form and any other written information to be provided to the participants. For studies involving Trust participants the Sponsor shall also ensure that the research study has R&D confirmation from the collaborating hospital trust/s.

Before participants can participate in research a valid informed consent must be obtained by the Research Team.

For healthy volunteer studies a separate participant consent form may be required for registration onto The Over-Volunteering Prevention System (TOPS database). A separate Participant Information Sheet with an explanation of the requirement to be registered on to the TOPS system should be provided to participants. Please see gSOP-038 Management of healthy volunteers in research studies.

3.0 APPLICABLE TO

This applies to all staff involved in clinical research sponsored/co-sponsored by UH, including: Chief Investigators, Principal Investigators, Research Fellows, Consultants, Statisticians, Clinical Trial Pharmacists, Research Managers, Research Nurses, Clinical Trial Practitioners, Allied Health Professionals, Trial co-ordinators/Managers, Clinical Studies Officers, Data Managers Research Assistants and Students.

4.0 RESPONSIBILITIES

The Sponsor shall ensure that a valid informed consent was obtained for all participants before recruitment and prior to carrying out any study specific procedures. Consent must be taken by the CI/PI or designated individual (DI).

The CI/PI/DI should fully inform the participant or, if the participant is unable to provide informed consent, the participant's legal representative, of all pertinent aspects of the trial including the written information given approval/favourable opinion by the ethics committee.

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The CI/PI shall ensure that participants have fully understood what they are consenting to. Consent is an ongoing process for the duration of the study. The participant should be followed up after being given information as to their decision to take part in the study and this should provide an opportunity for any further questions to be discussed. The Sponsor shall maintain overall responsibility for the consenting process.

The Sponsor/investigator may delegate parts of the informed consent duties to appropriately trained and qualified members of the research teams. Staff delegated to consenting shall have a valid GCP certificate. Delegation shall be documented on the study delegation log held in the Trial Master File (TMF).

The research personnel directly involved in the consenting process must personally sign and date the consent forms. They must also make a record in the participant's medical notes, of discussions related to the clinical trial with the participant and any further contact. If the participant decides not to consent a record of this should be recorded in the participant's medical records. If appropriate, the CI/PI may sign/countersign the consent form. All personnel who have completed/signed a consent form must have completed the study delegation log, which shall be countersigned/dated by the CI/PI. The CI/PI or DI should also ensure that PIS contain contact details for nominated personnel within the research team.

All research personnel with consenting responsibility shall ensure that the original copy of the research consent form is held in the Trial Master File (TMF)/Investigator Site File (ISF). Copies of signed consent form may be held in the medical notes and/or TMF and a copy must be provided to the participant. Staff must also ensure appropriate recording of all informed consent discussions in the patient medical records.

5.0 PROCEDURE

5.1 Considerations Before Starting Clinical Trials

5.1.1 The Sponsor/PI shall provide copies of all written informed consent forms and any other written information e.g. PIS to the CTSN and R&D office if applicable. All subsequent versions must be submitted as substantial amendments.

5.1.2 All written informed consent forms and any other written information e.g. PIS must have approval from ethics. All subsequent versions must also receive ethics approval as substantial amendments. Blank copies of all versions should be held in the TMF.

5.1.3 None of the written information relating to the trial shall unduly influence or coerce the trial participant or participant's legal representative.

5.1.4 The written information shall be in a non-technical language, easily understandable to the trial participant or the participant's legal representative or the impartial witness. It is recommended that the template provided by Health Research Authority (HRA)/Research Ethics Committee (REC) should be consulted during the preparation stages.

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5.1.5 The Sponsor/PI shall ensure that the study teams are adequately trained in obtaining and documenting a valid informed consent. Particular training needs must be met in describing technical languages involved in complex interventions, unlicensed Investigational Medicinal Product (IMP), invasive assessment methods, randomisation and other trial methodologies. In addition specific training in obtaining informed consent in a paediatric setting or for adults who lack consent should be given if applicable.

5.1.6 In order to obtain consent, the delegated staff member shall be familiar with the protocol, risks and benefits associated with the study and the peripheral and altruistic nature of the research. The delegated staff member shall be effectively trained in communicating all aspects of the study in a non-technical and understandable language.

5.1.7 The PI must ensure teams are adequately trained in clearly documenting the consenting process in participant records and other trial related documentations.

5.1.8 The Sponsor/PI must ensure R&D confirmation from the collaborating hospital trust/s is in place for the research study before participants are consented.

5.2 Obtaining Informed Consent from Trial Participants

5.2.1 Consenting participants shall be carried out in stages, allowing sufficient time between each stage. Stages shall include preliminary discussion, further discussion & provision of written information (e.g. PIS) and final consent.

The participant must be allowed sufficient time between each stage for understanding the provided oral and written information. The original research consent forms should be held within the TMF/ISF. A copy should be held within the participant's medical notes and a copy provided to the participant.

Under emergency situations, the consenting methods may vary. If prior consent from the participant was not available, the participant's legal representative must be consulted. If neither the participant nor the legal representative was available, the participant maybe enrolled as described in the protocol and/or elsewhere. This must be supported with documented approval from the ethics committee, to protect the rights, well-being and safety of the trial participants. The investigator shall abide by institutional policies and regulatory compliance.

5.2.2 In order to obtain a valid informed consent, the following best practice guidelines shall be considered:

- Early discussion with participants
- Answering questions fully by a qualified member of the research team
- Providing adequate information to make an informed decision
- Participant must not be under any pressure or duress
- Participant must be competent to make an informed decision
- Make sufficient notes of all discussions in participant's notes
- PIS should be used to enhance the participant's understanding of research however should not be used as a substitute for discussion

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5.2.3 The Sponsor/PI must ensure overall control for the informed consent process. However, the PI may delegate parts of the consenting process to adequately trained and qualified personnel. The investigator shall ensure that the delegated responsibilities are documented, dated and signed by the nominated personnel and a confirmation signature from the Investigator in a 'delegation of responsibilities log'. A copy shall be retained in the TMF.

5.2.4 The PI shall ensure that a written informed consent form was signed and personally dated by the subject or participant's legal representative.

5.2.5 An explanation of the standard treatment shall be provided to the subject prior to detailed discussions of experimental research (clinical trials). The subject shall be fully informed that their level of standard care shall not be affected irrespective of whether they decide to participate in research study or not.

5.2.6 The written information sheet and the informed consent verbal discussion shall contain the key points included in GCP.

5.2.7 The patient or legal representative shall be provided with written information such as the PIS and any other relevant materials to read at their own pace.

5.2.8 Further information sessions should be setup to allow discussion with the participant and to encourage questions. This may be in the form of an appointment or a telephone call. These discussions should also be annotated in the participant's medical record. The investigator should ensure participants fully understand all aspects of the research study including what the subject's responsibilities are.

5.2.9 If the participant's first language was not English, provisions for translational service must be considered.

5.2.10 If consent is to be taken from minors or adults who lack capacity, several other criteria must be considered. Please refer to relevant guidance and other applicable paediatric regulations.

5.2.11 Obtaining consent is an ongoing process and if the research study protocol or any PISs contain significant amendments (e.g. significant issues with regards to patient's safety), participants may in some cases need to be re-consented. This shall be determined by the Sponsor and ethics committee.

6.0 RELATED DOCUMENTS

- gSOP-01- SOP on SOPs
- gSOP-06- TMF/Site File
- gSOP-07- Research Training
- gSOP-20- Participant Information
- HRA guidance on information sheets and consent forms
- gSOP-038 Management of healthy Volunteers in Research Studies

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7.0 APPENDICES

- Appendix 1 - Definitions
- Appendix 2 - Key Points of ICH GCP Guidance on Informed Consent

8.0 VERSION HISTORY

Revision Chronology:		
Version Number	Effective Date	Reason for Change

9.0 AUTHORSHIP & APPROVAL

Author

Signature

Date

Pro-Vice Chancellor (Research & Enterprise) Approval

Signature

Date

10.0 AGREEMENT

Please detach and retain in your training files

I have read and understood the contents and requirements of this SOP (gSOP-04-01) and accept to follow UH policies in implementing it.

<p>Recipient</p> <p>Signature:Date:</p> <p>Name & Position:</p>

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Appendix 1: Definitions

Adverse Event (AE)

Any untoward medical occurrence in a subject to whom a medicinal product has been administered, including occurrences which are not necessarily caused by or related to that product

Chief Investigator (CI)

A Registered Physician, Dentist, Pharmacist or Registered Nurse who has overall responsibility for the conduct of the trial.

Clinical Trial

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or control) to evaluate the effects of those interventions on health outcomes.

Clinical Trial of Investigational Medicinal Product (CTIMP)

A study that looks at the safety or efficacy of a medicine/food stuff/placebo in humans as defined by the Medicines for Human Use Regulations (2004).

Delegated Individual (DI)

An individual delegated by the PI to carry out their task(s).

Good Clinical Practice (GCP)

As defined in the Regulations.

International Conference on Harmonisation (ICH)

The ICH produced a series of guidelines in 1996, E6 being the guideline on Good Clinical Practice, otherwise known as (ICH-GCP).

Investigator Site File (ISF)

The file(s) held at each site taking part in the trial which hold the essential trial document set necessary for local approval and trial conduct at site.

Patient Information Sheet (PIS)

A document that explains all relevant study information to assist the trial participant in understanding the expectations and requirements of participation in a clinical trial.

Principal Investigator (PI)

A Registered Physician, Dentist, Pharmacist or Registered Nurse who has responsibility for the conduct of the trial at a host site.

Site File

Site Files are held by the Principal Investigator at sites and contain copies of the essential documents, local approvals, signed consent forms and completed data forms.

The Regulations

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Medicines for Human Use (Clinical Trial) Regulations 2004 transposed the EU Clinical Trials Directive into UK legislation, as Statutory Instrument 2004 no 1031. This became effective on the 1st May 2004. An amendment to implement Directive 2005/28/EC was made to the Regulations as Statutory Instrument 2006 no 1928.

Trial Master File

The Trial Master File (TMF) will be held at the principal site by the sponsor, Chief Investigator or at the co-ordinating Centre. The TMF should contain all essential documents defined as documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. A Trial Master File should be set up at the beginning of a trial and maintained up-to-date throughout the trial until trial conclusion.

For trials currently running, it is recommended that Section 8 of the ICH-GCP Guideline is followed as guidance in order to meet statutory requirements. However, some of the documents listed may not be available or applicable in many non-commercial trials. The appropriate documentation will vary according to the trial and sponsor requirements.

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Appendix 2: Key points of ICH GCP Guidance on Informed Consent

This document refers to the ICH GCP Guidance on informed consent of trial subjects. Key points are listed below:

- Subjects shall be provided with what the trial involved, explanation of the parts that are experimental and other relevant background information.
- Why the subject/legal representative was approached and the purpose of the trial and eligibility criteria.
- Subject/legal representative must be ensured that the trial participation and related activities will be confidential. However, subjects should be informed that their medical records and other trial related documents will be accessed by research staff and other related personnel such as regulatory authorities, monitors, auditors and ethics committee for verification of trial data. The subject must authorise such access in the form of written consent, personally signed and dated.
- An explanation of the trial treatment(s), details of any medications, details of any invasive procedures, and the probability of random assignment to each treatment. If a placebo or use of medication outside licensed indication was involved, the subject should be provided with clear explanation of what that entails.
- An explanation of foreseeable risks or inconveniences to the subject and, where applicable, to any embryo, foetus, or nursing infant.
- An explanation of the expected benefits and altruistic nature of research must be provided. If the subject was not to gain any clinical benefit from the study, this should be explained.
- Subject/legal representative should be made aware of any available alternatives and the risks/benefits related to these.
- An explanation of compensation and/or care and supporting treatment available to the subject in the event of trial related injury must be explained.
- The anticipated prorated payment or travel expenses, if any, to the subject for participating in the trial.
- An explanation for use and storage of the collected biological samples (e.g. blood, tissue) must be provided. Appropriate use of these and supporting written consent must be obtained in compliance with the Human Tissue Act.
- Subject/legal representative must be advised that the trial participation is voluntary and that the subject may refuse to take part or to stop participation in the trial at any time.
- Subject must be informed of their responsibilities of participation in a trial, the duration of the trial, the likely number of trial participants, and the responsibilities for reporting any adverse

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events to the study team immediately to ensure their safety and that of other participants. If applicable, the subjects must be advised to provide the emergency card during every hospital admission to alert the study team.

- Subjects must be provided with details of the study team and an emergency contact number.
- Subjects must be informed that they will be provided with up-to-date information of all trial related issues and if necessary, the protocol and/or patient information sheets may be amended. In some cases, the subject may need to be re-consented. The subject should be provided with copies of all up-dated consent forms and PIS.
- Subjects must be informed that following consent, under certain cases, they might not be able to continue with the trial. If they failed to meet eligibility criteria at a later stage following diagnostic tests or other foreseeable circumstance and/or reasons under which the subject's participation in the trial may be terminated.

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