

## LOUGHBOROUGH UNIVERSITY RESEARCH OFFICE STANDARD OPERATING PROCEDURE

### Loughborough University (LU) Research Office SOP-1021 LU

### Informed Consent for NHS Research Sponsored by Loughborough University

**Effective Date: January 2016**

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#### **1.0 Introduction**

This Standard Operating Procedure (SOP) describes the process of obtaining informed consent from a study subject for all research sponsored by Loughborough University (LU). Informed consent is fundamental to research and must have been given prior to **ANY** study related procedures.

#### **2.0 Scope**

This SOP applies to all individuals involved in any research sponsored by LU, and includes individuals undertaking research at other sites in multicentre research studies.

#### **3.0 Definition**

Informed consent means that "the decision to take part in the trial is given freely after the subject (or person with parental responsibility or a legal representative) has been informed of the nature, significance, implications and risks of the trial" [European Medicines Agency - ICH Topic E6 \(RI\) Guidelines for Good Clinical Practice](#) – Section 4.8

The informed consent process begins with giving information to the subject, detailed discussion and clarification of that information and finally receiving verbal and written consent.

Further information regarding informed consent can be obtained by reviewing the [Medical Research Council Website](#).

The National Research Ethics Service (NRES) recommend the use of a template for writing an information sheet and consent form which can be found on the [HRA Website](#).

Research guidelines or good clinical practice (ICH-GCP) confirm that the Chief Investigator has overall responsibility to ensure that all consent processes are undertaken by suitably qualified and trained professionals. Additionally, a Principal Investigator (PI) has overall responsibility for the consent process at their individual site. However, the PI may delegate this task to a suitably qualified Sub-Investigator or other suitably trained professional. It is important to remember that the PI and CI remain ultimately responsible even when tasks are delegated. They must therefore assure themselves that those delegated with the responsibility are competent.

It is expected that the study documentation submitted detail the general policy for consent in a specific study and outline the types of personnel, and procedures involved.

**Written informed consent must be given prior to the conduct of any study related procedures.**

#### **4.0 Procedure**

All individuals identified as being appropriately qualified and trained to obtain consent in a study must be listed on the Delegation of Authority and Signature Log prior to them conducting any study related procedures.

All study personnel who are identified on the Delegation of Authority and Signature log as being responsible for obtaining informed consent, must ensure that they are completely familiar with all aspects of the study described in the latest version of the protocol, plus any protocol amendments, as approved by the Sponsor, NHS Trust and Research Ethics Committee. It is the responsibility of the CI to ensure that all sites are informed of any amendments to documentation throughout the lifetime of the study. Additionally, it is the responsibility of the PI to ensure that all site personnel are kept informed of any amendments and all study personnel must ensure that they are working to the most recent version. It is essential that local procedures are followed in respect of documentation required for approvals for staff working on individual studies.

The current, approved Participant Information Sheet (PIS) and Informed Consent Form (ICF) must be available during the consent process.

The Patient Information Sheet must include a contact number allowing the subject to contact a member of the research team.

#### **4.1 Consent Form**

The consent form must be printed on Local NHS Trust headed paper. The correct study title must be clearly visible and the correct version of the form used.

Statements to say that the subject has had the study fully explained to them, by whom, that the risks, benefits and treatments have been discussed, explained in

detail, and all the subjects' questions have been satisfactorily answered must be included.

It must state that agreement to participate is voluntary and that subjects are free to withdraw at any time without it affecting their medical care.

It must state that their medical records and / or data may be reviewed by authorised personnel of the study team, NHS Trust, Sponsor, Research Ethics Committee or Regulatory authorities, and that confidentiality will be maintained at all times.

Suggested wording: "I understand that relevant sections of my medical notes and/or data may be looked at by responsible individuals from the study team, the Sponsor, Research Ethics Committee, NHS Trust or from regulatory authorities where it is relevant to my taking part in the research. I give permission for these individuals to access my records."

Where identifiable data is to be stored at a different location to the NHS Site where original consent was obtained i.e. on University servers, or at a CTU etc, consent must be obtained

**NB: A consent form constitutes identifiable data.**

One copy of the PIS and ICF must be given to the subject preferably at the same time as the consent process has taken place. It is recognised that this may not always be possible, and in these circumstances a discussion must take place to agree an appropriate solution with the Sponsor. It is essential that the subject copy also includes their unique study number, so that if they need to contact the study team, they are able to be easily identified.

One copy of the PIS and fully signed ICF must be filed in the subject medical notes where appropriate. When this is not possible or appropriate, an alternative must be discussed and agreed with the Sponsor during the Sponsor review and risk assessment process.

The original of the PIS and ICF must be placed in the Investigator Site File. The ICF should always be filed with the PIS upon which the consent is based. It is recognised that this is not always possible or practical. In these circumstances, an alternative must be discussed and agreed with the Sponsor.

Care must be taken to ensure that the ICF makes reference to the most up to date PIS. It is recommended that when amending the PIS, the ICF version is also changed to match.

The subject must be provided with 'sufficient time' to read the information provided and to allow an opportunity for discussion of the study with family and friends or a general practitioner. It is expected that the process of consent and provision of time to allow a subject adequate time for consideration and a decision to participate is detailed in the study application documentation. It is important to remember that the process reviewed and given a Favourable Opinion by the Research Ethics Committee, and approved by the Sponsor and NHS Trust must be the process followed during the conduct of the study. Any deviations from this agreed process must be recorded in accordance with the Identifying and reporting deviations and serious breaches of GCP and / or the protocol SOP 1013 LU

In some circumstances it may not be possible to allow the approved length of time for consideration prior to consent. In these cases, the reasons for changing the approved

process for consent must be discussed with the Sponsor PRIOR to consent being obtained. If authorised, the outcome of this discussion must be documented and filed in the Investigator Site File (ISF) and Sponsor file. Retrospective approval for changes to the originally approved consent process must then be sought from the Research Ethics Committee and NHS Trusts where appropriate.

Each subject must personally sign, initial and date the ICF. Please note, the consent boxes must **NOT** be ticked.

The ICF must be personally signed and dated in black biro by the authorised researcher who conducted the informed consent discussion and by the subject. Each should clearly print their name by their signature.

The informed consent process should not cease once the ICF has been signed. The practice of giving information to the subjects should be an on-going process. This is particularly important with the introduction of protocol amendments and the availability of new information, which may be relevant to the subject's willingness to continue in the study.

In certain circumstances it may be necessary to re-consent all subjects on an amended consent form in order to continue involvement with the study. A discussion and decision about the requirements for re-consenting subjects will form part of the Sponsor Approval process for amendments.

All revised forms must be approved by the Sponsor, Research Ethics Committee and the NHS Trust prior to use in the study. Informed consent should be reaffirmed at each subsequent appointment even if no amendments have been made. This must be documented in the patient notes and / or on the Case Report Form.

#### **4.2 Consent process for adults consenting for themselves**

Subjects who are potentially eligible are identified and approached. Information to potential subjects should be delivered in a confidential manner respecting their dignity. Verbal and written explanation of the study must be provided in an appropriate format. Time must be allowed for questions to be fully answered.

Information imparted must not contain language that causes the subject to waive any legal rights, or that releases the Chief Investigator, Principal Investigator, Institution or Sponsor from liability for negligence.

When describing the study the person obtaining the consent should explain:

- That the trial involves research
- Confidentiality will be maintained throughout the study should they participate and that medical records will be reviewed only by authorized personnel
- Details of study design and drug/placebo use including known safety profiles
- Number of anticipated people taking part in the study
- Duration of the study, number of study visits involved (where and by whom), subject responsibilities.
- All procedures e.g. tests required as part of study
- Potential benefits and risks as result of subject participating
- Alternative treatment available
- Availability of compensation

- Participation is voluntary and the right to withdraw
- Participation payment (if appropriate)
- Details of study conclusion
- Funders and personnel who have reviewed the appropriateness of the study to be conducted.

This is not an exhaustive list.

Potential subjects will be given time to read and understand the information sheet and consent form. Questions regarding their participation will be answered. Without coercion, the person obtaining informed consent will ask the potential subject to sign the ICF relating to the study if they agree to participate and the researcher believes participation is not contrary to their best interests as a patient.

#### **4.3 Consent process for adults who lose capacity following initial decision to consent**

If a capable adult gives informed consent to take part in a trial, but subsequently becomes unable to give informed consent by virtue of physical or mental incapacity, the consent previously given when capable remains legally valid.

If a capable adult refuses informed consent, and subsequently becomes unable to give informed consent the refusal is legally binding. The individual cannot be entered in to the trial by seeking consent from a legal representative.

#### **4.4 Consent process for adults who lack capacity (i.e. adults who are unable to consent for themselves).**

There must be reasonable grounds for believing that research of comparable effectiveness cannot be carried out if the study has to be confined to, or relate only to, persons who do not have capacity to consent to taking part in it.

All research studies must comply with the Mental Capacity Act.

In all research the benefits to the subject must outweigh the risks or burdens, or the research must be of minimal risk, minimally intrusive and minimally interfere with the subjects rights.

Further advice on the consent of adults lacking capacity can be found in the toolkit on the [HRA website](#)

#### **4.5 Consent process where a witness is required**

In some cases, subjects will be capable of consenting for themselves but may not be able to read. In addition, there may be occasions where a subject is fully capable but for any number of physiological reasons are unable to sign a consent form themselves. This may include occasions where tremors are too severe or writing is impossible. If it is likely that subjects will present regularly with this type of situation, it is advisable to include a consent form that allows witnessed consent at the outset. The documentation must be explicit about the process to be used in assuring that the subject fully understands and the witness attests to this by signing the witness consent form.

Occasionally it will be necessary for a witness to be involved in the consent of a subject on an ad-hoc basis. The reasons behind a witnessed consent must be fully documented in the subject's notes and included in the Case Report Form. If it is considered likely that this may be repeated more frequently, then a substantial amendment must be submitted to include witness consent. If it is considered unlikely and rare, then the single occasion may be documented and an amendment will not be required.

#### **4.6 Consent process for minors**

To involve a minor in research the child may consent for themselves if they are deemed competent. Dependent on the study this may be a common-sense decision, assessed clinically or assessed by a competence tool. It is advisable to obtain parental consent also in most cases.

A person with parental responsibility or a legal representative should always be approached if available to obtain consent.

The child can however, refuse to participate or withdraw independently and by any form of communication i.e. their withdrawal can be behavioural.

Further advice on the consent of minors can be found on the [MRC Website](#).

#### **5.0 Assent**

In some circumstances, such as research in urgent care situations i.e. Cardiac Catheter Laboratories, the process of fully informed consent may not be possible prior to study related procedures taking place. In these situations, a process of verbal consent (Assent) to a study may be adopted, provide that at a later pre-determined time, fully informed written consent follows.

A short version of the PIS must be used to provide a brief explanation about the essential elements of the study to the subject allowing them to decide whether they wish to participate in the research. If they decide to participate, Verbal Assent will be taken and documented in the medical notes by the researcher/medic taking Assent. It is expected that as a minimum the following information is recorded:

- Time of Assent
- Date of Assent
- Name of Person obtaining Assent
- Version number of Short Version of PIS.

In addition, if the medic is not named on the Delegation of Authority & Signature Log the Assent Authority & Signature Log must be completed (Appendix A). It is understood that it may not always be possible to prospectively give authorisation for each individual named on the Assent Authority and Signature Log, but this must be completed by the CI/PI as soon as is possible following the Assent of a subject.

The Assent procedure must be followed up using the approved informed consent process within the timescale stated on the approved documentation. It is expected that the provision of Verbal Assent be discussed fully during the Sponsor Risk

Assessment and Approval Process. The use of an Assent process must have a Favourable Opinion from the REC and have approval from the NHS Trust.

If the participant is unable due to capacity, or unwilling to complete the informed consent process within the approved timescale, they must be considered to have withdrawn their consent for the study. Patient data collected only up to the point of withdrawal of consent can be utilized. The assent/consent process must be documented on the assent/consent log (Appendix B).

## **6.0 Withdrawal of Consent**

A subject has the right to withdraw from the trial at any time without being subject to resulting detriment. Following withdrawal, no further protocol procedures should be undertaken unless the subject agrees to being followed up for their own safety. Otherwise, any further treatment should continue outside the protocol.

It should be clearly documented whether the patient has withdrawn from treatment or treatment and follow-up. Also whether the patient withdraws consent for their samples to be used in this trial or future research. If their samples need to be destroyed this must be clearly documented.

## **7.0 Training**

To ensure that subjects receive the best possible care, it is vital that where appropriate, researchers receive specific training on the process of informed consent. It is accepted that all professionals undertaking clinical research must be compliant with the Research Governance Framework, and where appropriate ICH GCP.

Non-medics are allowed to obtain consent for research, if authorised to do so by the Sponsor, Chief Investigator & PI. However, delegation of this task will need to be approved by the NHS Trust and detailed in the application to the Research Ethics Committee.

If study personnel other than the Principal Investigator are obtaining consent, this must be documented on the study Delegation of Authority and Signature log (Appendix C).

The requirements for training for consent in research undertaken in Clinical Commissioning Groups (CCGs), or within the Community will be discussed with the Chief Investigator and relevant Research Governance personnel within the CCGs at the time of Sponsor Risk Assessment and Approval Process.

### **7.1 Process to be followed to obtain permission for Nurses, Non-Medics, & Allied Health Professionals receiving informed consent from subjects**

It is essential that a list of roles of study personnel who will be taking consent during the study is included in the study documentation and application process. It is not necessary for individuals to be named at the application stage.

It is the Chief Investigators responsibility to ensure that personnel listed to obtain consent are adequately qualified and trained in the study protocol to enable a fully informed consent process to take place. If during the course of the study, it is necessary to add additional roles to obtain consent, this must be submitted as a Non-Substantial amendment in accordance with SOP 1018 LU.

Where medics are listed as obtaining consent, it is expected that they are appropriately qualified by experience and qualification. It is not therefore mandatory for them to undertake additional consent training. However, if examples are identified during the Monitoring or Audit process that the documentation of consent is not adequate, corrective action required will include ALL personnel attending a consent training session.

Evidence of appropriate consent training must be retained within the Trial Master File / Investigator Site File.

## 8. Responsibilities:

	Responsibility	Undertaken by	Activity
1.	Chief Investigator	Chief Investigator	Detail on the application forms who will be obtaining consent
2.	Chief / Principal Investigator	Chief / Principal Investigator	Ensure the list of individuals authorised to obtain consent is documented on the study Delegation of authority and signature log (Appendix C) and have obtained written approval for their study role from R&D (where appropriate)
3.	Chief / Principal Investigator	Chief / Principal Investigator	Ensure all study personnel delegated to obtain consent have a comprehensive understanding of the study, are qualified by experience to do so and have obtained appropriate training
4.	Chief / Principal Investigator	Chief / Principal Investigator	Ensure that potential subjects are allowed sufficient time to consider taking part in the study and that the consent process given approval is followed.
5.	Principal Investigator	Principal Investigator &/or delegate	Ensure appropriate filing of PIS & ICF in line with this SOP
6.	Chief / Principal Investigator / Sponsor	Chief / Principal Investigator	Discussion with Sponsor between CI/PI about re-consent process if information emerges which may affect a subjects decision to continue in the study when an updated PIS is produced
7.	Research Governance Officer or delegate	Research Governance Officer or delegate	Assess relevant training & experience of study personnel to undertake their assigned study role
8.	Research Governance Officer or delegate	Research Governance Officer or delegate	Regularly review both the consent process and documentation to ensure compliance with relevant legislation and Standard Operating Procedures

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This table is used to track the development and approval of the document and any changes made on revised / reviewed versions



<b>DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT</b>			
<b>Author / Lead Officer:</b>	Jackie Green		<b>Job Title:</b> Research Governance Officer
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<b>Date</b>	<b>Name</b>	<b>Dept</b>	<b>Received</b>





**Appendix C**

## DELEGATION OF AUTHORITY and SIGNATURE LOG

**Before completion read the instructions on the reverse of this document**

**1 Study Number Ref:**
**2 Principal Investigator:**

<sup>3</sup> PRINT Name	<sup>4</sup> Role*	<sup>5</sup> Delegated Study Task(s)	<sup>6</sup> From (Date)	<sup>7</sup> To (Date)	<sup>8</sup> Initials	<sup>9</sup> Numbers 0-9	<sup>10</sup> Delegate Signature and Date PI Signature and Date

**\*CI=Chief Investigator PI=Principal Investigator SI=Sub Investigator RF = Research Fellow RN= Research Nurse CRA = Clinical Research Associate P= Pharmacist, RA= Research Administrator HCA= Health Care Assistant S= Statistician Other**

**1 Eligibility Screening 2 Eligibility Confirmation 3 Informed Consent 4 Physical Examination (Medic only) 5 Obtaining Medical History 6 Randomisation 7 Blood Sampling 8 Processing Bloods 9 Evaluation of Trial Lab Results 10 Performing ECGs 11 Evaluating ECGs 12 Dispensing Study Medication 13 Administering Study Medication 14 Study Medication Accountability 15 Unblinding 16 CRF Completion 17 Data Query Resolution 18 Serious Adverse Event Reporting 19. Causality/Expectedness assessment (delegated medic only) 20 eSUSAR Reporting 21 CRF sign off 22 Site File Maintenance 23 EC Communication Other – Specify**

**Any person named on this log should NOT be entered into the study.**

## Delegation Log Guidance

All members of Staff **MUST** complete and sign and date the Delegation Log and have it countersigned and dated by the PI **BEFORE** they undertake any trial related procedures.

The Principal Investigator is responsible for conducting studies in accordance with the Protocol and is required to keep a log of all individuals to whom he/she has delegated a specific task within the study. Where a task is being delegated to the individual, they should be qualified by education, training and experience to perform the task. The principal investigator is responsible for ensuring all staff involved in the study have received adequate training, including any new staff who become involved after the study has begun.

All staff must have R&D Approval before they sign the Delegation Log. A signed and dated CV for each person listed on the delegation log must be filed in the Trial Master File/Investigator Site File.

The log must be reviewed for completeness and accuracy during the lifetime of the study. Final review and end dated must be added at study closure.

### Completion of the Log

If more than one log is required, the logs must be marked accordingly i.e. Page 1 of 2

1. Study Number: Insert REC reference number
2. Principal Investigator: Insert name of Principal Investigator
3. Staff member must **PRINT** their name in this column
4. Staff member should enter their role in the study using the abbreviations found in the roles section at the bottom of the form. Should your role not be listed it should be added to the roles list or entered in writing in this column.
5. The staff member should review the list of delegated duties on the log and enter the roles that they have adequate training and experience to undertake.
6. Write down the start date in the format DD-MM-YYYY
7. This column should only be completed if a staff member leaves the study or when the study closes. Enter the date format as DD-MM-YYYY
8. The staff member should enter their initials in this column
9. The staff member should write the numbers 0,1,2,3,4,5,6,7,8,9 in this column
10. The staff member should sign and date the greyed delegate signature line  
The PI should then countersign and date on the line below to document that the member has been delegated the duties listed.