



**UNIVERSITY OF LEICESTER
&
UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST
JOINT RESEARCH SUPPORT OFFICE
STANDARD OPERATING PROCEDURES**

**University of Leicester (UoL) Research Governance Office
SOP S-1021 UoL**

Version 3.1, September 2021

**Informed Consent for Research Sponsored by the University of
Leicester**

OFFICE BASE

Research Governance Office
Academic Department, Ground Floor
Leicester General Hospital
Gwendolen Road
Leicester
LE5 4PW

Effective Date: October 2021

1. INTRODUCTION

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

2. SCOPE

This SOP applies to all individuals involved in any research sponsored by the UoL, and includes individuals undertaking research at other sites in multicentre research studies where UoL is the sponsor.

3. 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 Health Research Authority (HRA) 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. 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 (Appendix 1) 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, HRA, NHS Trust, Research Ethics Committee and where appropriate the MHRA. 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 appropriate headed paper. The correct study title and IRAS number 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/samples are 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, specific consent must be obtained. In addition, where data/samples are to be shared externally to the NHS/Universities, including outside of the UK, explicit consent must be obtained. (It is advisable to include these clauses even when there is an intention to maintain anonymous transfers).

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 and IRAS 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.

Where the PIS and ICF are paper based, the original must be placed in the Trial Master File (TMF)/ Investigator Site File (ISF). 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 e.g. where patient medical records are not required as part of the source data. 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.

In cases where either an electronic version of the completed ICF is captured with the participant retaining the original or fully electronic consent is obtained, care must be taken to ensure that the process is fully quality controlled and an assessment is undertaken. The Sponsor must then agree the process to be implemented. This process must also be agreed by the relevant REC.

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, HRA 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 S-1013 UoL.

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 TMF/ISF and Sponsor file. Retrospective approval for changes to the originally approved consent process must then be sought from the Research Ethics Committee, HRA, NHS Trusts and MHRA where appropriate.

Where paper based consent is required, each subject must personally sign, initial and date the ICF. Please note, the consent boxes must **NOT** be ticked. This may vary where electronic consent is the approved process.

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 Green Light process for amendments.

All revised forms must be approved by the Sponsor, HRA, Research Ethics Committee, the NHS Trust and if appropriate the MHRA 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, study workbook and / or on the Case Report Form.

4.1.1 Attending research appointments in a FASTED state

Subjects are sometimes required to attend a research appointment where consent will be taken in a fasted state. This constitutes a research procedure and is prior to consent. Therefore, a subject will be required to provide pre-consent agreement. This must be documented and retained in the ISF/TMF. It is recommended that a tear-off slip is provided at the end of an invitation letter. An example is provided at Appendix 4.

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. Further information can be found in the [ICH GCP Guidelines 4.8.10](#).

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.

For Clinical Trials of Investigational Medicinal Products consenting of adults who lack capacity is governed by the Medicines for Human Use Regulations, not the Mental Capacity Act. Subject to advance refusal by the subject the consent of a personal or professional legal representative is required as per the SOP S-1034 UoL, Procedure for Involving Incapacitated Adults in Research Sponsored by UoL.

All other 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.

In some emergency research the subject may be temporarily incapacitated for example due to a stroke. The Statutory Instrument 2006. No 2984 allows for temporarily incapacitated adults to be entered into a Clinical Trial of an Investigational Medicinal Product if treatment is urgent; the nature of the study also requires urgent decisions and it is not reasonably practical to meet regulatory requirements provided that a Research Ethics Committee have given a Favourable Opinion for this approach.

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 including the option to have a witnessed consent at the outset should be considered and included in the study consent form. If this is identified during the delivery of the study, 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.

An example of a witness consent form can be found at Appendix 5 and witness statement example at Appendix 6. Where possible, provision for witness consent should be included in the study wide consent form to reduce the complexities of document control.

4.6 Consent process for minors

In a Clinical Trial of an Investigational Medicinal Product a minor is a person under the age of 16, for other types of research there is no legal age for consenting. To involve a minor in other 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 assent also in most cases.

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

To involve a minor in a Clinical Trial of an Investigational Medicinal Product, parental or legal representative consent must be obtained. The process to be followed must be approved by the Sponsor, HRA, NHS Trust and where appropriate the MHRA. The process must be given a Favourable Opinion by the Research Ethics Committee (REC).

The child can however, refuse to participate or withdraw from the trial 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 and further training may also be available via the [NIHR](#).

5. 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, provided 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 1). 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 Green Light Process. The use of an Assent process must have a Favourable Opinion from the REC and have approval from the NHS Trust, and where appropriate the MHRA.

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 3).

6. 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, treatment and follow-up

7. 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 relevant legislation and local policies. (Please refer to SOP S-1020 UoL Training for staff engaged in research sponsored by UoL).

The SOP S-1020 UoL allows non-medics 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 HRA 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 1).

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 Green Light Process,

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

Process for studies using Investigational Medicinal Products IMP

Written agreement for non-medics to obtain informed consent for studies using Investigational Medicinal Products must be obtained from the Sponsor, Chief Investigator and Principal Investigator before commencing the process.

The person to obtain consent must be aware of all the aspects of the study protocol, and have adequate clinical experience to enable them to answer questions from the subject.

Subjects in Phase 1 trials must not be consented by a Nurse, Non-Medic or Allied Health Professional.

7.2 Process for all studies

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. Staff who join the study following approval must be added

to the Delegation of Authority and Signature Log and the relevant training certificates must be retained.

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.

It is a mandatory requirement that any non-medic/allied health professional attends an appropriate Consent Training course. The UoL acknowledge the NIHR Consent Training course.

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

7.3 Process for Research Tissue Banks

A Research Tissue Bank (RTB) or Biobank is a collection of human tissue or other biological material, which is stored for potential research beyond the life of a specific project with ethical approval or for which ethical approval is pending.

It is a requirement that all staff involved in with an RTB **MUST** undertake the Research Tissue Bank-an introduction eLearning Module found on the HRA website.

<https://www.hra.nhs.uk/about-us/news-updates/research-tissue-banks-new-elearning-modules/>

The module has been designed to help research and development staff, tissue bank managers, designated individuals and other staff to be aware of the structure of RTBs and the regulations and ethics behind them. Copies of any training certificates should be made available in the individuals personalised training records and a copy given to the RTB manager.

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 1) 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

	Responsibility	Undertaken by	Activity
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 Manager or delegate	Research Governance Manager or delegate	Assess relevant training & experience of study personnel to undertake their assigned study role
8.	Sponsor / CI	Sponsor / CI	Ensure written confirmation that those delegated to obtain consent are received from the NHS Trust (where required)
9.	Research Governance Manager or delegate	Research Governance Manager or delegate	Regularly review both the consent process and documentation to ensure compliance with relevant legislation and Standard Operating Procedures
10.	Research Governance Manager or delegate	Research Governance Manager or delegate	Arrange 100% audit of all informed consent forms in studies using investigational medicinal products.

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

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT

Author/Lead Officer:	Cat Taylor
Job Title:	Head of Research Assurance
Reviewed by:	Research Sponsorship Management and Operations Group
Approved by:	Professor Nigel Brunskill 
Date Approved:	13/10/2021

9. REVIEW RECORD

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
July 2015	2	Wendy Gamble	Amendment to 4.1 and 7.2.
Oct 2016	3	Diane Delahooke	Change logos, HRA addition and section 4.1.1, addition of provision of electronic consent.
Sept 2021	3.1	Cat Taylor	Administrative changes and addition of Consent process for Research Tissue Banks

10. DISTRIBUTION RECORD

Date	Name	Department	Received