

University of Leicester and University Hospitals of Leicester NHS Trust joint Research Support Office Standard Operating Procedures

University of Leicester (UoL) Research Governance Office

SOP S-1021 UoL

Informed Consent for Research Sponsored by the University of Leicester

Office Base

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This SOP will be implemented in line with this document's effective date for all UoL Sponsored research still in set up. For active clinical research that is already in the recruitment phase (or further) at the time of implementation, this SOP must be implemented within 3 months of the effective date.

Please note the appendices associated with this SOP may be subject to interim changes. Please ensure that appendices are downloaded from the RGO webpages prior to use to ensure the latest version of the document is being used.

1.0 Purpose and Scope

This Standard Operating Procedure (SOP) describes the process of obtaining informed consent from a study subject. Informed consent is fundamental to research and must have been given prior to any study related procedures taking place. This SOP applies to all individuals involved in research Sponsored by the University of Leicester (UoL), including individuals undertaking research at other sites in multi-centre research studies in England, Wales and Northern Ireland. For research taking place in Scotland, and involving those who lack capacity to consent for themselves and/or involving children, the HRA website should be consulted.

2.0 Introduction

Informed Consent is the process by which subjects voluntarily confirm their willingness to participate in a study, having been informed of the full details of the project.

Typically, informed consent is a three-step process which involves;

1. The giving of information to the subject
2. Having a detailed discussion and providing clarification of the information
3. Receiving the subjects verbal, written and/or electronic consent.

The Health Research Authority (HRA) recommend the use of a template for writing a participant information sheet and consent form. The Sponsor have created a suite of templates which must be used when creating your participant documents, these are available from the Research Governance Office (RGO) SharePoint [webpages](#). Further information regarding informed consent can also be obtained from the [Medical Research Council Website](#) and [HRA website](#).

Research guidelines or Good Clinical Practice (ICH-GCP) confirm that the Chief Investigator (CI) has overall responsibility to ensure that all consent processes are undertaken by suitably qualified and trained personnel. Additionally, a Principal Investigator (PI) has overall responsibility for the consent process at their individual site. They may delegate the task of obtaining informed consent to suitably qualified or trained personnel. However, it is important to remember that the CI and PI retain overall responsibility for ensuring that the correct and approved process has been followed, even when tasks are delegated. They must therefore assure themselves that those delegated with the responsibility are competent.

It is expected that the Sponsor and ethics application detail the specific process for consent in a study, and outlines the types of personnel, and procedures involved.

Informed consent must be obtained prior to the conduct of any study related procedures.

3.0 Procedure

All individuals identified as being appropriately qualified and trained to obtain informed consent in a study must be listed on the Delegation of Authority and Signature Log (DoA) (Appendix 1), and have informed consent as a delegated task prior to them performing

this task. Study personnel must ensure that they are completely familiar with all aspects of the study described in the current version of the approved protocol.

It is the responsibility of the CI (or their delegate) 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 CI/PI/delegate to ensure that all personnel are kept informed of any amendments, and all personnel must ensure that they are working to the current approved protocol. 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. In most cases, a copy of the PIS should be provided in advance of the informed consent discussion/process.

The PIS must include contact details allowing the subject to contact a member of the research team.

3.1 Consent form

Where a paper format is used, the consent form must be printed on appropriate headed paper with the study title clearly visible. The HRA require the IRAS number, document version number and date of the document to be in the footer of the document. For electronic consent, the format must allow identification of the organisation (as appropriate), the title, IRAS number and the document version number and date.

The consent form must contain;

- A statement to say that the subject has had the study fully explained to them, that the risks, benefits and treatments have been discussed, and all the subjects' questions have been satisfactorily answered
- A statement that agreement to participate is voluntary and that subjects are free to withdraw at any time without it affecting their medical care
- A statement 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
- Where 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 for this must be obtained
- Where data/samples are to be shared externally to the NHS/University, 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
- When samples or data are to be stored after the study, for which some has been collected with an intention to use in other studies, explicit consent must be obtained

Suggested wording for ICF development is available on our ICF templates accessible via the Research Governance webpages.

NB: A consent form constitutes identifiable data.

3.2 The consent process

The subject must be provided with 'sufficient time' to read the participant information, and given an opportunity to discuss the study with others. It is expected that the process of consent and the time period allocated to participants regarding their decision to participate is detailed in the Sponsor and ethics application.

The process that is reviewed and approved by the Sponsor and regulatory authorities must be followed during the conduct of the study. Any deviations from this approved process must be discussed with the Sponsor and will be recorded in accordance with the 'Identifying and reporting deviations and serious breaches of GCP and/or the protocol' SOP S-1013 UoL. Documentation and correspondence relating to deviations must be filed in the TMF/ISF and Sponsor file. It is expected that changes to the original approved consent process must be sought from the Sponsor and regulatory authorities via an amendment.

The informed consent process must be documented in a detailed and chronological manner in the subject's medical records, study workbook and/or on the Case Report Form as contemporaneously as is feasible. Where others such as personal or nominated consultee, professional representative or a witness have played an active role in assisting the subject, their involvement as either an advocate or witness should also be documented. We encourage the use of template stickers or continuation sheets for documenting the process of consent within the medical notes to aid the consistency of the information which is provided. The templates can then be populated with the specific detail relating to the consent process for any given subject. An example consent annotation sticker is available in Appendix 7

The informed consent process does not cease once the ICF has been signed. The practice of giving information to the subjects should be an on-going process. Informed consent should be reaffirmed at each subsequent appointment/contact with the subject (i.e., in the case of telephone follow-up calls, for example). It is particularly important to confirm continued consent to participate following the implementation of amendments, the implementation of urgent safety measures, 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 subjects on an amended ICF in order to continue their involvement with the study. A decision about the requirements for re-consenting some or all subjects will form part of the Sponsor Green Light process for amendments.

Re-consent should be considered for all active subjects. There may be instances where the amendment is not relevant to the subject (e.g. where the new protocol procedure amendment is to occur at a time point in the study that the subject has already passed).

The new versions of the ICF and PIS must be localised, as appropriate and a copy stored within the TMF/ISF. The previous versions should be marked as superseded. This is undertaken by striking a single diagonal line across the front page of the old document and marking as 'superseded', and be signed and dated by the person superseding the document.

Where either an electronic version of the completed ICF is captured with the participant retaining the original, or where fully electronic consent is obtained, care must be taken to ensure that the process is fully quality controlled.

All revised documentation must be approved by the Sponsor and regulatory authorities prior to use in the study.

In the case of a subject being potentially screened and enrolled into more than one trial, consultation and approval from both PIs and the Sponsors is required in advance of informed consent being obtained. These discussions should be clearly documented in the medical records and will be handled on a case-by-case basis.

3.2.1 Paper-based Informed Consent

Where paper-based consent is undertaken, the consenting researcher must;

- Ask the subject to read and then initial next to all the statements on the consent form **Note: Ticks or crosses in the statement boxes are not acceptable and will render the consent as invalid**
- Ask the subject to clearly print their full name, and sign and date the consent form
- Clearly print their full name, and sign and date the consent form
- File the original 'wet ink' signed ICF in the TMF/ISF
- File a copy of the PIS and fully signed ICF in the subject's medical notes
- Provide a copy of the fully signed consent form to the subject

The ICF must be completed in black biro. When any of the above are not possible or appropriate, an alternative must be discussed and agreed with the Sponsor. This should happen during the Sponsor review, and where relevant, the risk assessment process.

In the case of re-consent, the consenting researcher must conduct a consultation with each active participant to ensure they are made aware of any changes and are able to ask any questions in order to make an informed decision regarding whether to provide consent and continue in the study, or to withdraw. They must then follow the consent process as detailed above.

3.2.2 Electronic Informed Consent

The MHRA and HRA released a Joint Statement on "Seeking Consent by Electronic Methods" in September 2018. Where electronic consent is being considered for a study, the process should be in adherence with this statement. The joint statement confirms that electronic methods may be used for seeking, confirming and documenting informed consent in research studies. This includes the utilisation of online text or multimedia approaches as the main method of delivery of study information to potential subjects of a research study. For example, an electronic device such as a smartphone, tablet or computer may be used to convey information related to the study and to seek and/or document informed consent.

It must be taken into consideration that this method may unintentionally discriminate against potential participants who cannot use such technology. Alternative paper-based methods should be available for those unwilling or unable to use electronic methods.

The full statement can be found on the HRA [website](#). Additional information can also be found on the following [link](#).

Electronic methods of documenting consent can be considered to be in writing. This is undertaken by the use of an electronic signature. Electronic signatures can be classified as “simple”, “advanced” or “qualified” (defined below). The type of electronic signature that should be used in a study depends on whether the recruitment and consent procedures taken as a whole (and considered as part of a proportionate approach) mean that you:

- Can trust that the person who signed is who they say they are
- Can trust that the consent form they signed hasn't been altered
- Can trust when the signature was applied
- Can demonstrate that trust if required.

Electronic signatures

Definitions;

- Simple electronic signatures: This could be a finger/stylus drawn signature, typed name, a tick box and declaration, a unique representation of characters or fingerprint scan.
- Advanced electronic signatures: Uniquely linked to the signatory and capable of identifying the signatory, allow the signatory to retain control, and are linked to data within the signature that can detect any changes made.
- Qualified electronic signatures: an advanced electronic signature uniquely linked to the signatory that is created by a qualified electronic signature creation device, and which is based on a qualified certificate for electronic signatures.

Electronic signatures in CTIMP studies

The participant must be informed of the nature, significance, implications and risk of the trial in an interview with the investigator, or another delegated member of the research team. The interview should involve two-way communications in real time and allow confirmation of the subject's identity.

Information about the trial does not have to be in writing and can be provided using electronic methods however special attention should be paid to the information needs of specific subject population(s).

A copy of the ICF, either physical or electronic, should be provided to the subject.

For Type A studies which involves risks no higher than that of standard medical care, any simple electronic signature may be used (including typewritten or scanned signatures).

For CTIMPs involving risks somewhat higher (Type B trials) or markedly higher (Type C trials including Phase I studies) than that of standard medical care typewritten or scanned images of handwritten signatures should not normally be

used. eSignatures that involve tracing the subjects handwritten signature using a finger or stylus or biometric eSignatures should be used, as these allow direct comparison with eSignature/wet-ink signatures used for audit purposes or GCP inspection.

In clinical trials where consent is given remotely, it may not always be possible to verify that the participant is who they say they are. In such circumstances an advanced or qualified electronic signature should be used. Where a subject is required at some time point to visit a study site for purposes of the trial, then verification can be done in person using the information from official photo ID.

Electronic signatures in Non-CTIMP studies

A simple electronic signature may be adequate for the majority of non-CTIMP research that involves only negligible or minimal risk.

Where the research involves more than minimal risk or burden, simple eSignature that involve the participant tracing their handwritten signature using a finger or a stylus or biometric eSignature should be considered, as these allow direct comparison with wet signatures previously used by the subject.

For postal/online surveys or self-administered questionnaire-based research where identifiable personal data are to be collected, the subject must be able to actively signify their consent. This can be achieved by providing an explicit consent statement and a tick box within the questionnaire. In such cases a handwritten or biometric signature is not required.

3.2.3 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. In such instances, a subject will be required to provide a 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 in Appendix 4.

3.3 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. It is recommended that in most cases a minimum of 30 minutes is allocated for the process dedicated to obtaining consent which should be reflected in the IRAS Form (A18), SoE/SoECAT and study protocol.

Information 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 study/trial involves research
- Confidentiality will be maintained throughout should they participate and that medical records will be reviewed only by authorised personnel
- Details of the design and drug/placebo use including known safety profiles
- Number of anticipated people taking part
- Duration, number of visits involved (where and by whom), subject responsibilities
- All procedures (e.g. tests) required
- Potential benefits and risks as a result of participating
- Alternative treatment available
- Participation is voluntary and the right to withdraw
- Participation payment and compensation (if appropriate)
- Details of what will happen at the end of participation
- Funders and personnel who have reviewed the appropriateness of the study/trial to be conducted.

This is not an exhaustive list. Further information can be found in the [ICH GCP Guidelines 4.8.10](#).

For subjects where English is not their first language, it is important that the information is available in a language understandable to eligible subjects. Where PIS translation to other languages and/or use of an interpreter is required, this should have been considered and relevant provision described as part of the Sponsor and ethics application process. Where an interpreter is to be utilised, this must be a Trust approved interpreter, using family members and members of the research team is not appropriate.

Potential subjects must be given time to read and understand the PIS and ICF. 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.

3.4 Consent process for adults who lose capacity following initial decision to consent

If a capable adult gives informed consent, 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 study/trial by seeking consent from a legal representative.

3.5 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 CTIMPs, consenting of adults who lack capacity is governed by the UK Medicines for Human Use Regulations, not the Mental Capacity Act. Provided there is no evidence of advanced refusal by the subject, the consent of a personal or professional legal representative is required as per 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 CTIMP 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. Once capacity is regained the subject must be consented as detailed in the application process. Where consent is withheld, the subject must be withdrawn. Samples and data collected up to this point may be retained with the consent of the subject or legal representative.

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

3.6 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 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. 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. Where witness consent is required, please contact the RGO.

3.7 Consent process for minors

3.7.1 Consent for under 16s

The Medicines for Human Use (Clinical Trials) Regulations prohibit children under the age of 16 from giving consent to take part in a CTIMP.

Those who are able to give consent on behalf of children/young people, to take part in a CTIMP, in the UK are:

- A parent or someone with parental responsibility (agreement of only one parent is required)
- A personal legal representative (i.e., a person not connected with the conduct of the trial who is suitable to act as the legal representative by virtue of their relationship with the child/young person, and is available and willing to do so)
- Where a personal legal representative is not available, a professional legal representative (i.e., a doctor responsible for the medical treatment of the child/young person if they are independent of the study, or a person nominated by the healthcare provider).

A legal representative should only ever be approached if someone with parental responsibility cannot be contacted prior to the proposed inclusion of the child/young person, by reason of the urgent nature of the treatment provided as part of the trial.

You must ensure that parents or legal representatives:

- understand that you are asking them to give consent on behalf of the child/young person
- understand the objectives, risks and inconveniences of the trial and the conditions under which it is to be conducted
- have been informed of the right to withdraw the child/young person from the trial at any time
- have a contact point where further information about the trial can be obtained.

Children and young people should be involved in the decision-making process whenever possible. Researchers must ensure that they receive information about the trial, which is written in a format that is understandable to them.

The process to be followed must be approved by the Sponsor and regulatory authorities.

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 [HRA Website](#) and further training may also be available via the [NIHR](#).

3.7.2 Consent for over 16s

Young people over 16 are presumed to be capable of giving consent on their own behalf to participate in [CTIMPs](#).

Any young person, over 16, who is not considered capable of giving consent, should only be included in a CTIMP in the UK in line with the adult provisions of the Medicines for Human Use (Clinical Trials) Regulations.

3.7.3 Consent in non-CTIMPs

For non-CTIMP studies there is no statute governing a child's right to consent to take part in research.

3.7.4 Consent for research

In the absence of law relating specifically to research, it is commonly assumed that the principle of 'Gillick competence' can be applied not only to consent for treatment, but also to consent to participate in research.

Gillick competence helps people who work with children to balance the need to listen to children's wishes with the responsibility to keep them safe, and is often applied when trying to assess whether a child has the maturity to make their own decisions and to understand the implications of those decisions.

There is no set of defined questions to assess Gillick competency. Professionals need to consider several things when assessing a child's capacity to consent, including:

- the child's age, maturity and mental capacity
- their understanding of the issue and what it involves - including advantages, disadvantages and potential long-term impact
- their understanding of the risks, implications and consequences that may arise from their decision
- how well they understand any advice or information they have been given
- their understanding of any alternative options, if available
- their ability to explain a rationale around their reasoning and decision making.

A child/young person's right to give consent is dependent upon their capacity to understand the specific circumstances and details of the research being proposed, which in turn will relate to the complexity of the research itself.

Children and young people's competence may well be reflected in their ability, or otherwise, to understand and assess risk.

Competence to understand will be heavily influenced by how the information is presented to the child/young person, and the language used. You must ensure that you maximise a child/young person's chances of understanding what is involved in your study.

Remember that consent is not valid if a young person is being pressured or influenced by someone else.

Children's capacity to consent may be affected by different factors, for example stress, mental health conditions and the complexities of the decision they are making. The same child may be considered Gillick competent to make one decision but not competent to make a different decision.

If you don't think a child is Gillick competent or there are inconsistencies in their understanding, you should seek consent from their parents or carers before proceeding.

3.7.5 Consent for 16 and 17 year old's who lack capacity

If a young person, aged 16 and over, is deemed not to be competent to give consent themselves to participate in a non-CTIMP; you must proceed in line with the Mental Capacity Act (in England and Wales) or the Mental Capacity Act (Northern Ireland) 2016.

3.7.6 Children and young people's wishes and assent

Even when a child or young person is competent, it is still normally good practice to involve the family in the decision-making process, however, if the young person objects, you should respect their privacy.

Even when a child or young person is deemed not competent to make a decision for themselves, or in situations where they are not legally empowered to do so, (e.g. in a CTIMP), it is important that:

- you give the child/young person information about your study in a format which is understandable to them and which explains what is involved and the potential risks and benefits
- staff with experience of working with children/young people provide this information
- if the child/young person is capable of assessing the information provided you must consider their explicit wishes. This includes their refusal to take part, or desire to withdraw from the study
- it is usually inappropriate to ask very young children (e.g. under-fives) to sign an assent form, however their views should be considered.

Whenever practical and appropriate, a child's assent should be sought before including them in your research.

3.7.7 Consent for treatment

Common law presumes that young people aged between 16 and 18 are usually competent to give consent to treatment.

Case law suggests that if a young person has sufficient understanding and intelligence to understand fully what is proposed, and can use and weigh this information in reaching a decision (i.e. they are 'Gillick competent'), he or she can give consent to treatment.

When a child or young person is not competent, the Children Act and the Children Act (Northern Ireland) Order permits parents (and those with parental responsibility) to consent to medical treatment on their behalf. Consent of only one parent is required.

When a young person is believed to be competent, consent from those with parental responsibility is not legally necessary. However, the involvement of parents in decision-making is encouraged in most circumstances.

4.0 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, 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 DoA (Appendix 1) the Assent Authority & Signature Log must be completed (Appendix 2). 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 review and where appropriate the Sponsor Risk Assessment and Green Light Process. The use of an Assent process must have approval from the regulatory authorities and NHS Trust.

If the subject 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. Data and samples collected up to the point of withdrawal of consent can be retained. The assent/consent process must be documented on the assent/consent log (Appendix 3).

5.0 Withdrawal of consent

A subject has the right to withdraw from a study at any time without their future medical care or legal rights being affected. Following withdrawal, no further protocol procedures should be undertaken unless the subject agrees to being followed-up. Otherwise, any further treatment should continue outside the protocol.

It should be clearly documented whether the subject has withdrawn from treatment or treatment and follow-up. Data and samples collected up to the point of withdrawal should be retained.

6.0 Training

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. 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. SOP S-1020 UoL ‘Training for staff engaged in research sponsored by UoL’ should be consulted.

7.0 Responsibilities

Responsibility	Undertaken by	Activity
CI	CI/delegate	Detail on the Sponsor and ethics application who will be obtaining consent
CI	CI/PI	Ensure the list of individuals authorised to obtain consent is documented on the study Delegation of Authority and Signature Log (Appendix 1)
CI	CI/PI	Ensure all study personnel delegated to obtain consent have a comprehensive understanding of the study, are qualified by training and experience.
CI	CI/PI/delegate	Ensure that potential subjects are allowed sufficient time to consider taking part in the study and that the approved consent process is followed.
CI	CI/PI/delegate	Ensure appropriate filing of PIS & ICF in line with this SOP.
CI/Sponsor	CI/PI/Sponsor	Discussion with Sponsor between CI/PI about re-consent process if information emerges which may affect a subject’s decision to continue in the study when an updated PIS is produced.
CI	CI/PI/Sponsor/d elegate	Assess relevant training and experience of study personnel to undertake their assigned study role.
Sponsor/CI	Sponsor/CI	Ensure there is evidence of valid consent training where required (e.g. training certificate).
Sponsor	Sponsor	Regularly review both the consent process and documentation to ensure compliance with relevant legislation and Standard Operating Procedures.
Sponsor	Sponsor/delegat e	In accordance with a risk-adapted approach to monitoring and trial-specific monitoring plans, arrange a review of informed consent forms in studies using investigational medicinal products.

8.0 Development and approval record for this document

This table is used to track the development and approval of the document.

Author	Job title	Reviewed by	Approved by	Date approved
Cat Taylor	Head of Research Governance	UoL Research Sponsorship Management and Operation Group (RSMOG)	Professor Nigel Brunskill 	18/05/2023

9.0 Review record

This table is used to track the changes made on revised / reviewed versions.

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
May 2023	4.0	Cat Taylor	Administrative and formatting changes to improve accessibility of SOP and appendices Addition of information relating to the electronic provision and receipt of consent. Clarification around eConsent processes and the inclusion of minors in research. Removal of training requirements (moved to SOP-1020). Updates to the table of responsibilities. Update to appendices; Appendix 1 DoA table reformatted for ease of use, updated instructions and roles and delegated duties table. Addition of Appendix 7 – consent and eligibility medical note annotation example. Other appendices changes were mostly administrative. Removal of Appendix 5 Witness consent form template and Appendix 6 Consent Witness Statement. Replaced with a request for researchers to contact the RGO where witness consent is required. Update to UoL logo on appendices.