1. Introduction

This Standard Operating Procedure (SOP) describes the process of obtaining informed consent from a study subject for all research sponsored by the University Hospitals of Leicester NHS Trust (UHL). 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 UHL, and includes individuals undertaking research at other sites in multicentre research studies where UHL is the sponsor.

3. Definition

Informed consent is a " Process by which a subject voluntarily confirms his/her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subjects decision to participate. Informed Consent is documented by means of a written, signed and dated informed consent form" (ICH-GCP E6 1.28 1996)

The informed consent process begins with giving information to the subject by either a written paper version and/or by use of electronic/multimedia delivery .Having a detailed discussion, providing clarification of that information and receiving verbal and written consent/ electronic 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 (CI) 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 Sub-Investigator or other professional with the appropriate training. It is important to remember that the CI and PI 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 a Delegation of Authority Log (DOA) (Appendix 1). In addition, there is functionality available on the EDGE system to provide an Electronic Delegation of Authority Log (eDOA). UHL have agreed that with effect from 1st April 2018, any research team wishing to utilise this option may do so. When using the eDOA the research team must implement a study

Signature Log (Appendix 7) Guidance on how to use the eDOA can be found within EDGE General Documents – eDOA Working Instructions. It is important to remember that the DOA or eDOA & Signature Log must be completed prior to individuals conducting any study related procedures.

All study personnel who are identified on the DOA or eDOA 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, and throughout the study 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

Where a paper format is utilised, the consent form must be printed on appropriate headed paper. For electronic consent the format must allow identification of the organisation (as appropriate). The correct study title & the 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, 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, and where applicable without it affecting their medical care.

It must state that their medical records (where applicable) 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).

When samples or data are to be stored after the study for which same has been collected with an intention to use in other studies, explicit 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 & 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. This should happen during the Sponsor review, and where relevant the risk assessment process.

Where the PIS and ICF are paper based, the original must be placed in the TMF/ 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 a paper and/or electronic version of the completed ICF form are 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 and an assessment is undertaken. The Sponsor must then agree the process to be implemented. This process must also be agreed by the relevant Research ethics committee, HRA and the regulatory authority (MHRA) where appropriate. Further information on obtaining electronic signature for consent can be found in section 4.1.1 of this SOP.

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 UHL.

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 undertaken the authorised researcher who conducted the informed consent discussion will ask the participant to read then initial any statements required by the consent form. Ticks or crossed in the statement boxes are not acceptable. Once completed the participant should clearly print their full name and sign and date the consent form. The researcher will then clearly print their full name and sign and date the consent form.

The informed consent process must be documented in a detailed and chronological manner in the subject's medical records. Where others such as personal/ professional representatives or where a witness have played an active role in assisting they subject, then their involvement as either an advocate or witness should also be documented.

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. These discussions should be clearly documented in the medical records and should be handled on a case by case basis.

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/ Implementation of urgent safety measures where the availability of new information, may be relevant to the subject's willingness to continue in the study.

In certain circumstances it may be necessary to gain new consent from 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.

Re-consent should be considered/ occur for all active subjects. There may be incidences 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 authorised researcher will 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.

The new version of the consent and patient information sheets must be localised, as appropriate and a copy stored within the TMF/ISF. The previous version 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 signed and dated by the person superseding the document.

Once re-consent is completed the subject should be given a copy of the new PIS/ICF and the re-consent process documented in the subjects medical records. A copy of the PIS/ICF should also be filed in the medical records. The new version of consent should be filed with the older version in the TMF/ISF.

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 medical records, study work book, and / or on the Case Report Form.

4.1.1 Electronic Informed Consent

The MHRA and HRA released a "Joint Statement on Seeking Consent by Electronic Methods" document in September 2018.
The full statement can be found on the HRA website as follows:
https://www.hra.nhs.uk/about-us/news-updates/hra-and-mhra-publish-joint-statement-seeking-and-documenting-consent-using-electronic-methods-econsent/

Where electronic consent is being considered for a study, the process should be in adherence with this statement.

Additional information can also be found by following this link:
http://www.transceleratebiopharmainc.com/initiatives/econsent

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 the use 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 participant who cannot use such technology. Alternative paper method should be available for those unwilling or unable to use electronic methods.

Informed consent must be recorded in "writing". Electronic methods of documenting consent can be considered to be in writing. This is undertaken by the use of an electronic signature. They are classified as "simple", "advanced" or "qualified". 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

There are three groups of electronic signature as follows:

- 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 based on a qualified certificate for electronic signatures.

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 patient populations and those of individuals.

A copy of the consent 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 eSignatures.

For all type B and Type C studies including Phase 1 healthy volunteer trials, simple e|Signatures 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. Typewritten or scanned images of handwritten signatures should not normally be used.

In clinical trials where consent is given remotely, it may 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 the subjects 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.

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 e-signature that involve the participant tracing their handwritten signature using a finger or a stylus or biometric e-signature should be considered as these allow direct comparison with wet signatures previously used by the subject.

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

4.1.2 Attending research appointments in a FASTED state

Subjects are sometimes required to attend a research appointment where consent will be taken in a fasted stated. 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 6.

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. 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), any site contracts or Statement of Activity.

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 they are being invited to participate in research
- Confidentiality will be maintained throughout the study should they participate and that where applicable medical records will be reviewed only by authorised personnel. In addition the circumstances where disclosure may be necessary
- 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/access to study results
- 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.

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 and use of an interpreter is required, this should have been considered and relevant provision described as part of the application process Where an interpreter is to be utilised this must be a Trust approved interpreter, using family members is not appropriate.

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.

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 study, 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 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 give fully informed consent.

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. Where the use of a personal or professional legal representative is required, this should be undertaken as described in the application process and as per UHL Policy Procedure for Involving Incapacitated Adults in Research Sponsored by UHL.

All other research studies must comply with the Mental Capacity Act.

Persons who are incapable of giving legal consent should be given special protection. Such persons may not be included in trials if the same results can be obtained using persons capable

of giving consent. Normally these persons should be included in trials only where there would be grounds for expecting a direct benefit to the subject, therefore outweighing the risks.

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. 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

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 identified during the delivery of the study, 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.

An example of a witness Consent Form can be found at Appendix 4 and example witness statement at Appendix 5. Where possible, provision for witness consent should be included in the study wide consent form, in order to reduce 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, 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 study 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 CRNEM Learning

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 DOA / eDOA the Assent Authority & Signature Log (AAS) 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 AAS, but this must be completed by the 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 Risk Assessment and Green Light Process. The use of an Assent process must have a Favourable Opinion from the REC approval from the HRA, 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 utilised. 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 study at any time without being subject to resulting detriment. Following withdrawal, no further protocol procedures should be undertaken unless the subject agrees to be 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 study or future research. If their samples need to be destroyed this must be clearly documented.

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-1008 UHL Training for staff engaged in research sponsored by UHL)

The SOP S-1008 UHL 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 DOA/eDOA (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 studies 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 C I 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. Members of staff who join the study following approval must be added to the DOA/eDOA 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 training..

It is not mandatory for medically qualified personnel to undertake additional consent training, but it is highly recommended. However, if examples are identified during monitoring or audit processes that the documentation of consent is not adequate, corrective action required will include ALL personnel attending a consent training session.

It is UHL Trust policy to encourage nurses, non-medics and Allied Health Professionals to obtain consent. In order to facilitate this, it is a mandatory requirement that each individual attends an appropriate consent training course. UHL acknowledge the NIHR consent raining course, in addition to the course provided by the UHL Research Training Team. However, if an external

training package has been accessed, including the NIHR training, there is a requirement for the UHL consent training assessment test to be completed to obtain an accepted certificate.

At the current time, it is not possible for individuals at NHS Organisations outside of UHL to access the UHL consent training, unless they are able to attend a session at UHL. If this isn't feasible or realistic given geographical restrictions or availability of resource, UHL as Sponsor will discuss local provision of appropriate consent training with individual R&I Offices at host sites.

Evidence of appropriate consent training must be retained within the T M F / I S F.

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)
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.	Head of Research Operations or delegate	Head of Research Operations 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 as appropriate (where required)
9.	Head of Research Operations or delegate	Head of Research Operations or delegate	Regularly review both the consent process and documentation to ensure compliance with relevant legislation and Standard Operating Procedures
10.	Head of Research Operations or delegate	Head of Research Operations or delegate	Arrange audits of informed consent forms in accordance with Appendix 2 SOP S-1007 UHL

9. Legal Liability Statement

Guidelines or Procedures issued and approved by the Trust are considered to represent best practice. Staff may only exceptionally depart from any relevant Trust guidelines or Procedures and always only providing that such departure is confined to the specific needs of individual circumstances. In healthcare delivery such departure shall only be undertaken where, in the judgement of the responsible healthcare professional it is fully appropriate and justifiable – such a decision to be fully recorded in the patient's notes and in the research site file.

10. Supporting Documents and Key References

SOP 1008 UHL Training for Staff Engaged in Research

SOP 1013 UHL Serious Breaches

SOP 1007 UHL Monitoring

Appendices 1, 2, 3, 4, 5, 6, 7

8. Key Words

Research, Innovation, Volunteers, Participants, Informed Consent, Trials, eDOA, DoA

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

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