UNIVERSITY OF LEICESTER, LOUGHBOROUGH UNIVERSITY
&
UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

JOINT RESEARCH SUPPORT OFFICE

STANDARD OPERATING PROCEDURES

UHL Research Support Office
SOP S-1006 UHL V10 September 2018

Standard Operating Procedure for Informed Consent for Research
sponsored by
University Hospitals of Leicester NHS Trust (UHL)

PCG Registration – C11/2014

OFFICE BASE
Research & Innovation
Leicester General Hospital
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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 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 (R1) Guidelines for Good Clinical Practice – Section 4.8

The informed consent process begins with giving information to the subject, having a detailed discussion, providing clarification of that information and 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 (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

The consent form must be printed on appropriate headed paper. 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 either an electronic version of the completed ICF form 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 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. Further information on obtaining electronic consent can be found by following this link: [http://www.transceleratebiopharmainc.com/initiatives/econsent/](http://www.transceleratebiopharmainc.com/initiatives/econsent/)

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 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.

Where a paper ICF process is to be used, the form 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 full 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 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.

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 work book, 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 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
• 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.

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 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 UHL Policy Procedure for Involving Incapacitated Adults in Research Sponsored by UHL.
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 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 no: 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. 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 qualification.

It is not mandatory for medically qualified personnel to undertake additional consent training, but it is recommended. 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 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 Training course, in addition to a 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 Trial Master File / Investigator Site File.

8. Responsibilities:

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Undertaken by</th>
<th>Activity</th>
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<tbody>
<tr>
<td>1. Chief Investigator</td>
<td>Chief Investigator</td>
<td>Detail on the application forms who will be obtaining consent</td>
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<tr>
<td>2. Chief / Principal</td>
<td>Chief / Principal</td>
<td>Ensure the list of individuals authorised to obtain consent is documented</td>
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<tr>
<td>Investigator</td>
<td>Investigator</td>
<td>on the study Delegation of authority and signature log (Appendix 1) and</td>
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<td>have obtained written approval for their study role from R&amp;I (where</td>
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<td>appropriate)</td>
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<td>3. Chief / Principal</td>
<td>Chief / Principal</td>
<td>Ensure all study personnel delegated to obtain consent have a</td>
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<td>Investigator</td>
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<td>comprehensive understanding of the study, are qualified by experience to</td>
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<td>do so and have obtained appropriate training</td>
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<td>4. Chief / Principal</td>
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<td>Ensure that potential subjects are allowed sufficient time to consider</td>
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<td>Investigator</td>
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<td>taking part in the study and that the consent process given approval is</td>
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<td>followed.</td>
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<td>5. Principal</td>
<td>Principal Investigator&amp;/</td>
<td>Ensure appropriate filing of PIS &amp; ICF in line with this SOP</td>
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<td>6. Chief / Principal Investigator / Sponsor</td>
<td>Chief / Principal Investigator</td>
<td>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</td>
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<td>7. Head of Research Operations or delegate</td>
<td>Head of Research Operations or delegate</td>
<td>Assess relevant training &amp; experience of study personnel to undertake their assigned study role</td>
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<td>8. Sponsor / CI</td>
<td>Sponsor / CI</td>
<td>Ensure written confirmation that those delegated to obtain consent are received as appropriate (where required)</td>
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<td>9. Head of Research Operations or delegate</td>
<td>Head of Research Operations or delegate</td>
<td>Regularly review both the consent process and documentation to ensure compliance with relevant legislation and Standard Operating Procedures</td>
</tr>
<tr>
<td>10. Head of Research Operations or delegate</td>
<td>Head of Research Operations or delegate</td>
<td>Arrange audits of informed consent forms in accordance with Appendix 2 SOP-S-1007 UHL</td>
</tr>
</tbody>
</table>

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.
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

<table>
<thead>
<tr>
<th>Author / Lead Officer:</th>
<th>Carolyn Maloney</th>
<th>Job Title: Head of Research Operations</th>
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<tr>
<td>Reviewed by:</td>
<td>R&amp;I Management Meeting</td>
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<tr>
<td>Approved by:</td>
<td>Professor Nigel Brunskill</td>
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<td>Date Approved:</td>
<td>17 DEC 2018</td>
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### REVIEW RECORD

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<th>Reviewed By</th>
<th>Description Of Changes (If Any)</th>
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<tr>
<td>March 2015</td>
<td>2</td>
<td>Carolyn Maloney</td>
<td>Changes to Logo and office names – amendment to 7.2</td>
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<tr>
<td>October 2015</td>
<td>3, 4 &amp; 5</td>
<td>Carolyn Maloney</td>
<td>Version of SOP to correlate with appendices</td>
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<tr>
<td>August 2016</td>
<td>7</td>
<td>CM, LW, JJ</td>
<td>Consistency check. HRA addition, addition of Pre-Consent proforma and addition of electronic consent provision</td>
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<tr>
<td>March 2017</td>
<td>8</td>
<td>CM</td>
<td>Update to Logo</td>
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<tr>
<td>March 2018</td>
<td>9</td>
<td>CM</td>
<td>Update and review. Addition of utilisation of EDGE eDOA</td>
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| Sep 2018    | 10           | CCL, JJ       | Update to logo  
Update to appendix 1 delegation log to include tasks related to medical devices |

### DISTRIBUTION RECORD:

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Any person named on this log must be added to the Project Site Level (RED) on the EDGE Database.

Delegation Log Guidance

All members of Staff MUST complete, sign and date the Delegation Log then have it countersigned and dated by the PI BEFORE they undertake any trial related procedures. All staff listed on the Delegation Log must also be added to the Project Site Level (RED) in the EDGE Database.

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

A signed and dated CV and copy of current relevant training certificates for each person listed on the delegation log must be filed in the Training repository within the individual record on EDGE. It is not necessary for these to be held within the TMF/ISF provided a file note directs to EDGE.

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

Completion of the Log

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

1. Study Number: Insert study reference number
2. Principal Investigator: Insert name of Principal Investigator
3. Staff member must PRINT their name in this column
4. Staff member should enter their role in the study using the abbreviations found in the roles section at the bottom of the form. Should your role not be listed it should be added to the roles list or entered in writing in this column.
5. The staff member should review the list of delegated duties on the log and enter the roles that they have adequate training and experience to undertake.
6. Write down the start date in the format DD-Mon-YYYY e.g. 01-Jan-2018
7. This column should only be completed if a staff member leaves the study or when the study closes. Enter the date format as DD-Mon-YYYY e.g. 01-Jan-2018
8. The staff member should enter their initials in this column
9. The staff member should write the numbers 0,1,2,3,4,5,6,7,8,9 in this column
10. The staff member should sign and date the greyed delegate signature line
The PI should then countersign and date on the line below to documents that the member has been delegated the duties listed.
Each person must complete their own entry and once named on this log should NOT be entered into the study.

<table>
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<tr>
<th>PI Signature and Date</th>
<th>Delegate Signature and Date</th>
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Before completion read the instructions

DELEGATION OF AUTHORITY AND SIGNATURE LOG

NHS Trust
University Hospitals

SHN
Assent Signature Log

Study Number:  
Study Title:  

Any individual taking assent for the above study that is not named on the delegation of authority list must complete this log.

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SOP S-1006 Appendix 2 Assent Signature Log  
Version 10 September 2018
Consent form template

The consent form template below will be suitable for many studies but may need alterations to be commensurate with your study and must be used in conjunction with the guidance given in https://www.hra.nhs.uk/planning-and-improving-research/best-practice/informing-participants-and-seeking-consent/

For some studies a fuller, itemised or hierarchical consent form may be needed to cover important issues, especially if additional elements are optional for the participant. These may include:

- additional invasive tests or samples required for study purposes only;
- consent to use of audio/video-taping, with possible use of verbatim quotation or use of photographs;
- transfer of data/samples to countries with less data protection;
- agreement to receive individual feedback from testing.
Centre Number:
Study Number:
Patient Identification Number for this trial:

WITNESS CONSENT FORM

Title of Project: [PROJECT TITLE]
Name of Researcher: [NAME OF CHIEF INVESTIGATOR]

1. I confirm that I have read and understand the information sheet dated [DATE] (version [VERSION NUMBER]) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from [COMPANY NAME], from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

4. I agree to my GP being informed of my participation in the study.

5. I agree to take part in the above study.

Name of Participant __________________________ Date ___________ Signature ________________

Name of Person taking consent __________________________ Date ___________ Signature ________________

Name of Consent Witness __________________________ Date ___________ Signature ________________
Consent Process Witness Statement

Study Title: ____________________________________________________________

Study Number: _________________________________________________________

Chief Investigator/Principal Investigator Name: _____________________________

Participant Unique Study Identifier: ________________________________________

Participant Name: _______________________________________________________

Reason for utilising witnessed consent: _____________________________________

I, (print witness name) __________________________________________ confirm that I / a member of the research team (print name of researcher) __________________________________ have read and explained the content of the patient information leaflet, version xxxxx, dated xx/xx/xx and confirm that (name of participant) ___________________________ has had any questions answered. I confirm that to the best of my knowledge (delete as appropriate) she/he understands this information and is willing to participate.

I confirm that the signature/mark represents the signature of her/him. (delete as appropriate)

Witness Contact Details:

Address: ______________________________________________________________

____________________________________________________________________

____________________________________________________________________

Telephone Number: ____________________________________________________

Email Address: _________________________________________________________

When completed: 1 for Patient; 1 for Site File; 1 to be kept with hospital notes

SOP S-1006 UHL Appendix 5 Consent Witness Statement
V10 September 2018
Consent Process Witness Statement Guidance

It is important to note the difference between a 'signature witness' and a 'witness to the consent process'. A 'signature witness' merely sees the participant sign consent, whereas a 'witness to the consent process' is present for the whole consent discussion.

ICH-GCP guidelines require an impartial witness if the consent giver (i.e. the participant or their legal representative) can't read (GCP 4.8.9). In such cases the witness must a) be present for the whole informed consent discussion and b) sign and date the consent form after the consent giver has done so. In signing the consent form the witness is attesting to the fact that all written information was accurately explained and apparently understood by the consent giver and informed consent was freely given by the consent giver.

The consent witness informed consent form and consent witness statement is NOT intended for use where a personal or professional legal representative are giving consent on behalf of the participant.

It is important that all fields are completed to ensure that identification of the study, Principal Investigator, witness and participant can be undertaken.

The name of the witness must be entered, along with the name of the researcher reading/explaining the study (where applicable)

The reason for utilising a witness must be recorded

Please indicate whether the witness or the researcher has read/explained the study
Please record the version number and date of the patient information leaflet provided to the participant

The witness contact details must be recorded for identification purposes

The original copy of the completed witness statement must be filed within the Investigator Site File along with the corresponding completed consent form and patient information leaflet, a copy must be given to the participant along with a copy of the corresponding completed consent form and patient information leaflet and a copy must be filed in the participant's medical records along with a copy of the corresponding completed consent form and patient information leaflet

Documentation of the consent/witness consent process must be recorded in the main body of the participant's medical records
Pre Consent Agreement - Fasting

Where there is a requirement that subjects present for screening in a fasted state, the ethics committee must be aware of and approve the offer to subjects to provide fasting samples upon screening. It may be inappropriate to do this with vulnerable groups such as the elderly.

If subjects do take up the offer of arriving fasted, then they should be warned about the possible consequences (dizziness etc. and in the case of diabetics the potential for low/high blood sugars).

The subject should be aware that they can take longer to think about the study and come back for a further visit should they not wish to undergo the consent process whilst fasting. Therefore failure to arrive for the screening visit in a fasted state would not preclude them from entering the study.

When these safeguards are in place then the risk to the subject is low. It is the subject's choice to decide whether or not to arrive for the screening visit having met the conditions.

Consideration should be given when writing protocols to ensure that they do not exclude subjects from screening simply because the testing conditions were not met at the initial visit. Processes should permit the required tests to be done at a later date, perhaps within a window defined as the screening visit, or at a subsequent visit.

At no time should it be suggested to a subject to begin a wash-out period, change a medication, or do anything that could affect his or her medical condition, safety or well-being, prior to having the full study explained and obtaining their written informed consent.
LETTER OF INVITATION

Reply slip. Please cut/tear off and return to the address above.

Study Title: xxxxxxxxxxxxxxxxxxx

- I have read the Patient Information Sheet Version XX Dated XX XX XXXX and am interested in taking part in the above study and agree to be contacted by the study team. I understand that I am under no obligation to take part in this study.

Please delete as appropriate:

- I agree to attending the screening visit in a fasting state as described in the above Patient Information Sheet.

- I would prefer to attend the screening non fasting and understand that this may require a further visit to complete screening requirements.

Name: ........................................................................................................

Address: ....................................................................................................

..................................................................................................................

..................................................................................................................

Telephone No: ............................................................................................

Signature ........................................................................................................

Date: ............................................................................................................

Agreement Invitation letter – Pre Consent Template  Appendix 6 to SOP S-1006 UHL Version 10 September 2018
**Signature Log – for use in conjunction with EDGE DOA**

<table>
<thead>
<tr>
<th>Study Number:</th>
<th>Study Title:</th>
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Where the EDGE eDOA is to be used, this Signature log must also be completed.

<table>
<thead>
<tr>
<th>Print Name</th>
<th>Signature</th>
<th>Write numbers 1 through to 9</th>
<th>Initials</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example</td>
<td>Mrs Tiggywinkle</td>
<td>1,2,3,4,5,6,7,8,9</td>
<td>GT</td>
<td>01/02/2018</td>
</tr>
</tbody>
</table>