1. Introduction

This Standard Operating Procedure (SOP) describes the process of obtaining informed consent from a study subject for all research that is HOSTED by the University Hospitals of Leicester NHS Trust (UHL) or for where the UHL is a Research SITE. 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 HOSTED by the UHL or where the UHL is a Research SITE.

3. Definition

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

The informed consent process begins with giving information to the subject, detailed discussion and clarification of that information and finally receiving verbal and written/Electronic/virtual consent (E-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 the Principal Investigator (PI) has overall responsibility for the consent process at their individual site. However, the PI may delegate this task to a suitably qualified Sub-Investigator or other suitably trained professional. It is important to remember that the PI remains ultimately responsible even when tasks are delegated. They must therefore assure themselves that those delegated with the responsibility are competent.

Written informed consent must be given prior to the conduct of any study related procedures (unless deferred consent).

4. Requirements

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) prior to them conducting any study related procedures. It is expected that the Sponsor will provide an appropriate log to record this detail but in the absence of a Sponsor provided document the UHL version may be used. An example can be found at Appendix 1.

All study personnel who are identified on the Delegation of Authority log as being responsible for obtaining informed consent, must ensure that they are completely familiar with all aspects of the study described in the latest version of the protocol, plus any protocol amendments, as approved by the Sponsor, HRA, the Trust and where appropriate the MHRA. It is the responsibility of the PI to ensure that all personnel are informed of any amendments to documentation throughout the

lifetime of the study. The PI must ensure that all personnel 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. It is expected that every individual working on the study and listed on the DOA are also recorded within EDGE for the specific study. For purposes of clarification EDGE is the Trust research electronic database.

The current, approved Participant Information Sheet (PIS) and Informed Consent Form/E-consent (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 Approvals

Where a paper format is used, the consent form must be printed on appropriate headed paper. The correct study title must be clearly visible and the correct version of the form used. Where UHL satellite or Alliance sites are being used as recruitment sites then the relevant headed paper for that site may be used (e.g. Loughborough Hospital).

The consent form used must be the current approved version. Where required approval must be provided by some or all of the following organisations prior to use:

- Research Ethics Committee (REC)
- Health Research Authority
- MHRA
- Confidentiality Advisory Group (CAG)
- R&I Authorisation from the Trust

Further information about approvals can be found in SOP C-2008 UHL and SOP C-2011

Subjects who are potentially eligible may be identified and approached using the method agreed by the Research Ethics Committee (REC) and Health Research Authority (HRA).

4.2 Consent Administrative Process

4.2.1 Paper Format

Each subject must personally sign, initial and date the ICF. Please note, the boxes on the consent form must **NOT** be ticked.
The ICF must be personally signed and dated in black biro by the authorised researcher who conducted the informed consent discussion and by the subject. Each should clearly print their name by their signature.

4.2.2 Electronic Format

Electronic formats may vary from study to study, therefore the process of obtaining E-consent/virtual consent must be approved by the applicable regulatory bodies must be adhered to.

4.3 Filing of Evidence of Consent

4.3.1 Paper Format

One copy of the PIS and ICF must be given to the subject preferably at the same time as the consent process has taken place. It is recognised that this may not always be

possible, and in these circumstances a discussion must take place to agree an appropriate solution with the Sponsor. It is essential that the subject copy also includes their unique study number, so that if they need to contact the study team, they are able to be easily identified.

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

The original of the PIS and ICF must be placed in the Investigator Site File. The ICF should always be filed with the PIS upon which the consent is based. It is recognised that this is not always possible or practical. In these circumstances, an alternative must be discussed and agreed with the Sponsor. Care must be taken to ensure that the ICF makes reference to the most up to date PIS. It is recommended that when amending the PIS, the ICF version is also changed to match.

4.3.2 Electronic Format

Electronic formats may vary from study to study, therefore the process of obtaining E-consent/virtual consent must be approved by the applicable regulatory bodies must be adhered to.
Where E-consent/virtual consent is to be utilised the host organisation must be informed to ensure relevant privacy and IM&T processes are in place prior to trust authorisation. Relevant personal within Privacy and IM&T must be approached prior to Trust authorisation. The study specific information on E-consent/virtual consent will be obtained as part of the Capacity and capability process and recorded on EDGE within a specific attribute.

4.4 Ongoing Consent Process

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

In certain circumstances it may be necessary to re-consent all subjects on an amended consent form in order to continue involvement with the study.

All revised forms must be approved prior to use. Please see SOP C-2011 UHL for further details. It is recommended that informed consent is reaffirmed at each subsequent appointment even if no amendments have been made. This should ideally be documented in the patient records and / or on the Case Report Form.

5. Consent for adults who lose capacity following initial decision to consent

It is expected that the protocol / study documentation approved by the HRA will include information about the steps to take in this scenario. In cases where this information is not available, please consult with the Sponsor and where appropriate consult SOP S-1006 UHL where an acceptable process is outlined.

5.1 Consent for adults who lack capacity (i.e. adults who are unable to consent for themselves).

It is expected that the protocol / study documentation approved by the HRA will include information about the steps to take in this scenario. In cases where this information is not available, please consult with the Sponsor and where appropriate consult SOP S-1006 UHL where an acceptable process is outlined.

5.2 Consent where a witness is required

It is expected that the protocol / study documentation approved by the HRA will include information about the steps to take in this scenario. In cases where this information is not available, please consult with the Sponsor and where appropriate consult SOP S-1006 UHL where an acceptable process is outlined.

5.3 Consent for minors

It is expected that the protocol / study documentation approved by the HRA will include information about the steps to take in this scenario. In cases where this information is not available, please consult with the Sponsor and where appropriate consult SOP S-1006 UHL where an acceptable process is outlined.

6. Assent

It is expected that where Assent is provided prior to/ at the same time as fully informed written consent that the full process be documented in the Protocol or as a Study specific SOP / Working Instructions

7. Study related procedures prior to consent

As a general rule, no study related procedure must take place prior to consent. In some circumstances however, subjects are asked to attend the consent visit prepared for participation in the study. E.g. in a fasted state. It is expected that the Sponsor will provide a relevant proforma as part of the study documentation.

8. Withdrawal of Consent

A subject has the right to withdraw from the study at any time without any detriment to their future medical care. 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 as per normal care.

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.

9. Training on the Process of Consent

To ensure that subjects receive the best possible care, it is vital that where appropriate, researchers receive specific training on the process of informed consent. It is accepted that all professionals undertaking clinical research must be compliant with the Policy Framework for Health and Social Care, and where appropriate ICH GCP. (Please refer to SOP C-2005 UHL Training for staff engaged in research HOSTED by UHL)

The SOP C-2005 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 UHL R&I and detailed in the application to the REC & HRA.

If study personnel other than the Principal Investigator are obtaining consent, this must be documented on the study DOA.

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

9.1.1 Process for studies using Investigational Medicinal Products IMP

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

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

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

9.2.2 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 PI responsibility to ensure that personnel listed to obtain consent are adequately qualified and trained in the study protocol to enable a fully informed consent process to take place. Staff who join the study following approval must be added to the DOA and the relevant training certificates must be retained.

Where medics are listed as obtaining consent, it is expected that they are appropriately qualified by experience and qualification. It is not therefore mandatory for them to undertake additional consent training.

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 Monitoring and 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 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.

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

10. Responsibilities

	Responsibility	Undertaken by	Activity
1.	Principal Investigator	Principal Investigator	Detail on the Schedule of Events & Statement of activity the roles of study personnel at UHL.
2.	Principal Investigator	Principal Investigator	Ensure the list of individuals authorised to obtain consent is documented on the study Delegation of authority log (Appendix 1) and the individuals are listed in the EDGE record.
3.	Principal Investigator	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.	Principal Investigator	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.

	Responsibility	Undertaken by	Activity
5.	Principal Investigator	Principal Investigator&/or delegate	Ensure appropriate filing of PIS & ICF in line with this SOP
6.	Principal Investigator / Sponsor	Principal Investigator	Discussion with Sponsor between 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.	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

11. 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.

12. Supporting Documents and Key References

SOP Appendix 1

SOP C-2008

SOP C-2011

SOP C-2005

13. Key Words

Research, Innovation, Volunteers, Participants, ATIMPS, CTIMPS, Trials, Informed, Consent, E-Consent, ICH, GCP, DOA, ICF, PIS

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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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REVIEW RECORD			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**
June 2016	2	CM, LW, AG, SA CM	Changes to reflect new national requirements. Addition of HRA. Addition of 'pre-consent' proforma. Check consistency. Version of appendices to correlate with SOP.
February 2017	3	CM	Update to Logo
February 2019	4	CM, LW	Update of terminology. Remove details about requirements of Consent Forms, focus on recording rather than consent process.
Nov 2020	5	LW, JJ, AM	Reformatting, Updating SOP and adding process for E-consent

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