STU-SOP-TM-005 – Standard Operating Procedure on Consent for Adults Lacking Capacity

1. Purpose and Definitions

This Standard Operating Procedure (SOP) describes the procedure of obtaining consent for adults lacking capacity in a research project. This involves the process of giving information, requesting consent and how a consent decision will be recorded.

It is important to note that the research provisions in the Mental Capacity Act 2005 and the Adults with Incapacity (Scotland) Act 2000 do not apply to Clinical Trials of Investigational Medicinal Products (CTIMPs). The arrangements for adults unable to consent for themselves are covered specifically in the UK and EU legislation.

Definitions	
Capacity	The ability to use and understand information to make a decision, and communicate any decision made.
Competent adult	A person 'who has sufficient understanding and intelligence to enable them to understand fully what is involved in a proposed intervention will also have the competence to consent to that intervention' (Gillick MHA Code 36.38).
Personal consultee	Someone who knows the person who lacks capacity in a personal capacity, who is able to advise the researcher about the person who lacks capacity's wishes and feelings in relation to the project and whether they should join the research. A researcher should take steps to identify a consultee who has a role in caring for the person who lacks capacity or is interested in that person's welfare but is not doing so for remuneration or acting in a professional capacity (a "personal consultee").
Nominated consultee	Someone who is appointed by the researcher to advise the researcher about the person who lacks capacity's wishes and feelings in relation to the project and whether they should join the research.
Consent	For the purposes of this SOP, "Consent" may refer to informed consent or assent.

2. Background

Informed consent means that the decision to take part in the research project is given freely after the participant, or their consultee, has been informed of the nature, significance, implications and risks of participating in the research project. Informed consent should protect the participant's autonomy and their rights and wellbeing. It should be an ongoing process of information exchange for the duration of the research project.

Research projects other than CTIMPs conducted in adults who lack the capacity to consent for themselves as defined by the Mental Capacity Act 2005. Lack of capacity may be long-term (e.g. people with mental health issues) or short term (e.g. people in extreme pain or people who are unconscious or intubated).

To ensure that the dignity, rights safety and well-being of potential participants who cannot consent for themselves are protected, an advocate usually a personal legal representative or a professional legal representative is described in the legislation to determine who should be

approached to consider the inclusion of the adult lacking capacity in the research project.

The informed consent process and all material used must be approved by a Research Ethics Committee (REC) before use.

In obtaining and documenting informed consent, the research team must comply with Good Clinical Practice (GCP) and with the REC approved protocol.

3. Roles and Responsibilities

Sponsor is responsible for ensuring that the informed consent process for the research project complies with the relevant regulations and protocol, and that all relevant materials used are REC approved.

Chief Investigator (CI) is responsible for ensuring that the research project is conducted in accordance with the approved protocol by training the Principal Investigator (PI) and other staff at research sites. The CI is also responsible for ensuring that only REC approved informed consent documentation is used. This task may be delegated to the Trial Manager.

Principal Investigator (PI) at each research site is responsible for making sure that only individuals authorised (on the delegation log) and suitably trained and qualified are able to seek informed consent.

Trial Manager (TM) is responsible for managing the development and approval of the Consultee Information Sheet (CIS), and Consultee Informed Consent Form (CICF) and disseminating updates to sites when amendments have been made. The TM may also participate in training research site staff.

Authorised site research staff are responsible for discussing the CIS with potential participants and/or their representatives in a timely manner, discussing any queries, requesting consent and recording the consent decision before any research procedures or test commence.

Personal Consultees (personal legal representatives) are usually immediate family members of the potential participant and are responsible for making an informed consent decision on behalf of the potential participant once all information has been imparted and any questions have been answered.

Nominated Consultees (professional legal representatives) are usually the doctor with primary responsibility for the adult's medical treatment, or the person nominated by the relevant health care provider and are responsible for making an informed consent decision on behalf of the potential participant in the absence of any family members. If the legal representative is a medical person, they must be independent of the research project.

External use of SOP: this SOP and Associated Documents (AD) may be used for research projects not adopted by STU where Swansea University (SU) staff and associated NHS organisations require guidance. In such instances, oversight responsibility for any associated tasks will not be the responsibility of STU.

4. Procedure

Appendix 2 illustrates the process of seeking informed consent at research sites.

4.1 Preparation of the Consultee Information Sheets (CIS) and Consultee Informed Consent Forms (CICF)

4.1.1 Consultee Information Sheet (CIS)

The consultee should be given full and accurate information about the research project they are being asked to consider. The information must be presented in a form that they can understand. The information is usually presented as a CIS which must have been approved by a REC and should contain as a minimum the information found in the HRA Consultee Information Sheet Template (http://www.hra-decisiontools.org.uk/consent/examples.html).

Other forms of REC approved media may be used to inform the consultee of the research project. Any form of media used should outline what participation means in practice, the length of time they will be involved, where it takes place and what is involved.

4.1.2 Consultee Informed Consent Forms (CICF)

CICF should be version controlled and dated on locally headed paper and identify the unit or department conducting the research. The CICF must state the research project title and if a CTIMP list the EudraCT number as per the HRA Consultee Informed Consent Template (http://www.hra-decisiontools.org.uk/consent/examples.html).

4.2 Training site staff to take informed consent

Consent can be requested by any delegated member of the research team. For a CTIMP, confirmation of eligibility prior to consent is regarded as a medical decision and must be completed by clinically qualified individuals.

Site staff must be trained by the CI or other authorised person(s) on when to approach a consultee, what information they should provide (written and verbally), and how to record details of the consent decision.

4.3 Discussing the research project with the consultee

Authorised site staff should approach the consultee in accordance with the approved protocol and should discuss the research project with them in an unbiased manner using the CIS for information. The privacy, dignity and preferences of the potential participant should be taken into consideration and a private area sought for the discussions that take place.

The consultee must be informed of their right to withdraw the participant from the research project at any time. They should be given time to ask questions and consider their response before deciding on whether to agree to the potential participant being enrolled in the research project.

The protocol should stipulate how long the consultee has before they are asked to make a consent decision.

The process of seeking informed consent must also be documented in the participant's medical records or other source document (if applicable). The following information should be recorded:

a. the research project title and/or acronym
b. the version the consultee has been given
c. the date and time that the information was given

If a participant enrolled into a research project while lacking capacity regains their capacity, the consent process for adults with capacity (STU-SOP-TM-004) must be followed and the participant's decision to reconsent or withdraw documented.

4.4 Receiving consent

Only the most recently approved CICF may be used for recording informed consent.

Delegated site staff should approach the consultee at an appropriate time to discuss the research project. The protocol should describe how to record the decision to either decline or accept the invitation to participate.

If the consultee gives consent, they should initial the statements on the CICF as appropriate, sign and date the form.

Delegated staff should check that the form has been completed correctly before countersigning the form.

The screening log and any other relevant Case Report Forms (CRFs) should be updated with the consent decision.

For CTIMPs, and as applicable for other research projects, the date and time that the consultee consented to the project must be recorded in the participant's medical records.

4.5 Presumed Consent

An eligible potential participant may be enrolled into a research project on the basis of presumed consent. This should only happen if there is a time-sensitive action which must be performed and no practical way to receive consent within the required timeline.

Where presumed consent applies, the CI or delegate will approach the consultee as soon as possible thereafter to discuss the research project and receive a valid consent decision for the participant to remain in the research project.

The protocol and CIS will advise of any interventions which can be undertaken before consent has been received, particularly if the consultee has been approached about the research project but has not yet made a consent decision.

When possible, consent from the participant should be sought at an appropriate time during their recovery. The process as described in STU-SOP-TM-004 should be followed.

4.6 Evidence of consent provided

The original completed, signed and dated CICF should be placed in the Investigator Site File (ISF). The CICF must not be stored together with data from CRFs.

A signed and dated CICF should also be given to the consultee as either a photocopy, using carbonated paper or having them sign a second CICF.

The participant's medical records should be updated with all consent decisions, who provided them and the time and date. Copies of the CIS(s) and signed CICF(s) should also be filed in the medical records and sent to the participants GP if required by the protocol.

4.7 Seeking Consent Electronically

There may be some circumstances where it is appropriate to seek, confirm and document informed consent from potential participants electronically.

The MHRA and HRA have published a joint statement setting out the legal and ethical requirements for seeking and documenting consent using electronic methods. eConsent can be used to supplement or replace traditional paper-based approaches.

Electronic signatures 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.

Key points from the MHRA/HRA statement:

- Informed consent must be recorded 'in writing'. Electronic methods are considered to be 'in writing'.
- A copy of the signed consent form must still be provided to the participant, either physically or electronically.
- For Type A trials, or research projects with minimal risk, any **simple electronic signature** may be used (including typewritten or scanned eSignatures
- For Type B and Type C trials, or research projects involving more than minimal risk, simple eSignatures that involve tracing the participant's handwritten signature using a finger or a stylus or biometric eSignatures should be used as these allow direct comparison with eSignatures/wet-ink signatures used previously for audit purposes or GCP inspection.
  Typewritten or scanned images of handwritten signatures should not normally be used
- In clinical trials that are conducted remotely it may not always be possible to verify that the participant is who they say they are. In such circumstances it may be preferable to use an **advanced or qualified electronic signature**

4.8 Re-Consenting

The informed consent process does not cease once the consent form has been signed; the practice of giving information about the research project to the consultee of participants should be an ongoing process. It is important that ongoing verbal consent is confirmed as part of each research-contact where possible with the consultee.

When there is a significant change to the research project or the discovery of important new information that may be relevant, a revised CIS and CICF must be provided and written informed consent must be requested again from the consultee, as detailed above.

4.9 Withdrawal of consent

The consultee may withdraw their consent at any time during a research project without providing a reason(s) for their decision. Withdrawal must be documented on a withdrawal CRF and actioned as soon as practicable.

Following withdrawal, no further protocol procedures should be undertaken unless the consultee agrees to the participant being followed up for their own safety. The procedures for retaining data and samples already collected at the time of withdrawal must be clarified with the consultee or participant. This procedure must be documented.

Where the consultee or participant requests all data and samples be destroyed, there may be situations where, methodological legal, regulatory or clinical requirements would prevent the destruction of data and samples and the participant or consultee would be informed of such instances and advised that data will be held under quarantine conditions. If data and/or samples cannot be destroyed for practical reasons, the CIS should make this clear prior to consent being requested.

5. References

- Health Research Authority website (HRA) - http://www.hra.nhs.uk/
- Medicine and Healthcare products Regulatory Agency website (MHRA) - https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/services-information
- UK policy framework for health and social care research (2017) - https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
- UK Medicine for Human Use (Clinical Trials) Regulations 2004 - http://www.legislation.gov.uk/uksi/2004/1031/contents/made
- The Clinical Trials Toolkit - http://www.ct-toolkit.ac.uk/routemap/informed-consent/
- Mental Capacity Act 2005 http://www.legislation.gov.uk/ukpga/2005/9
- http://www.hra.nhs.uk/documents/2013/07/guidance-on-nominating-a-consultee-for-research-involving-adults-who-lack-capacity-to-consent.pdf
- HRA and MHRA joint statement on seeking and documenting consent using electronic methods (eConsent) https://www.hra.nhs.uk/about-us/news-updates/hra-and-mhra-publish-joint-statement-seeking-and-documenting-consent-using-electronic-methods-econsent/

It is assumed that by referencing the principal regulations that all subsequent amendments are included in this citation.

6. Associated Documents

Number	Title	Location
STU-AD-TMP-019	Delegation Log Template	Q-Pulse

7. Abbreviations

List of Abbreviations	
CI	Chief Investigator
CIS	Consultee Information Sheet
CRFs	Case Report Forms
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
CICF	Consultee Informed Consent Form
ISF	Investigator Site File
PI	Principal Investigator
PIS	Participant Information Sheet
REC	Research Ethics Committee
SOP	Standard Operating Procedure
STU	Swansea Trials Unit
TM	Trial Manager

8. Appendices

Appendix 1: Document History

Version No:	3	**Effective Date:**	22-Apr-2024
Description of changes:	Updated to SOP template v5 Typographical corrections		

Appendix 2: Developing the documentation, process and approvals for seeking and recording informed consent