STU-SOP-TM-004 – Standard Operating Procedure on Informed Consent from Competent Adults

Version No:	4	**Effective Date:**	17-Apr-2026
Description of changes:	SOP reviewed in light of clinical trial regulations 2025 and GCP updates. Specific references to QPulse as the QMS have been removed. We now only refer to a QMS system.		

List of Abbreviations	
CI	Chief Investigator
CRFs	Case Report Forms
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
ICF	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

1. Purpose and Definitions

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

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). Consent must be given freely by a person with the necessary mental capacity who has been adequately informed for it to be valid.
Informed consent	A person gives informed consent to take part in a clinical trial only if their decision: (a) is given freely after that person is informed of the nature, significance, implications and risks of the trial; and (b) either: (i) is evidenced in writing, dated and signed, or otherwise marked, by that person so as to indicate his consent, or (ii) (ii) if the person is unable to sign or to mark a document so as to indicate his consent, is given orally in the presence of at least one witness and recorded in writing

2. Background

Informed consent must be given by each participant before they can be enrolled in a research project. Informed consent means that the decision to take part in the research project is given freely after the participant 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 may opt for a layered approach in obtaining consent using multiple forms of information such as information sheets, videos, audio, brochures etc. so as not to overwhelm the participant.

The informed consent process and all material used must be approved by an ethics committee before use.

In obtaining and documenting informed consent, the research team must comply with Good Clinical Practice (GCP) and the process described in the protocol which has been REC approved.

For Clinical Trials of Investigational Medicinal Products (CTIMPs) consent must be conducted in accordance with the UK regulations.

Even though consent is not the legal basis for processing personal data for research, the common law duty of confidentiality is not changing, **so consent is still needed for people outside the care team to access and use confidential patient information for research**, unless you have support under the Health Service (Control of Patient Information Regulations) 2002 ('section 251 support') applying via the Confidentiality Advisory Group in England and Wales or similar arrangements elsewhere in the UK.

3. Roles and Responsibilities

The **Sponsor** is responsible for ensuring that the informed consent process for the research project is conducted in accordance with the approved protocol, principles of GCP and all relevant regulations, and that all materials used are REC-approved.

The **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 project locations. 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.

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

The **Trial Manager** (TM) is responsible for managing the development and approval of any patient facing information including the Participant Information Sheet (PIS), Informed Consent Form (ICF) and any other related documentation, and disseminating updates to project locations when amendments have been made. The TM may also participate in training research staff at project locations.

Authorised project location research staff are responsible for discussing the PIS with potential participants in a timely manner, discussing any queries, requesting consent and recording the consent decision before any research procedures or tests commence

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 1 illustrates the process of seeking informed consent at research locations. Guidance published from the HRA and MRC at https://www.hra-decisiontools.org.uk/consent/ should be considered.

4.1 Preparation of documentation/media

4.1.1 Participant Information Sheet (PIS)

Potential participants should be given full and accurate information about the research project they are being asked to consider. Consent procedures should be proportionate to the risk, complexity and specific needs of the project. The information must be presented in a form that the reader can understand. The information is usually presented as a PIS which must be version controlled and dated on locally headed paper and identify the unit or department conducting the research. The PIS must also have been approved by a REC and should contain as a minimum the information found in the HRA Participant Information Sheet Templates at https://www.hra-decisiontools.org.uk/consent/examples.html

Other forms of media may be used to inform potential participants of the research project such as videos and posters. 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. REC approval is also required for these media.

In June 2017 the HRA issued guidelines (https://www.hra.nhs.uk/about-us/news-updates/hra-publishes-new-proportionate-consent-guidance/) encouraging researchers to take a more proportionate approach to the process of seeking consent to participate in research to ensure simple research designs could be explained without the need for complex information sheets.

General Data Protection Regulations (GDPR) guidance should also be followed when developing PISs (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/).

4.1.2 Informed Consent Forms (ICFs)

ICFs must be version controlled and dated on locally headed paper and identify the unit or department conducting the research. The ICF must state the research project title and IRAS ID (the EudraCT number if applicable), as per the HRA Consent Form Template (http://www.hra-decisiontools.org.uk/consent/examples.html). The consent form should be fitted to one page wherever possible so that the signatures are on the same page as the consent statements.

Where eConsent is to be used (see Section 4.7), the software managed by STU should use a paper ICF as its basis and be fully tested (see STU-SOP-DMS-009). Staff at project locations will provide the portal for the participant to sign, either face to face on an electronic device, or by emailing them a link with their permission. Access to a paper ICF should always be offered.

4.2 Training project location staff to take informed consent

Consent can be requested by any authorised member of the research team who is appropriately qualified by education, training or experience to undertake this task. They should also have up to date GCP training.

Staff at the project locations must be trained by the CI or other authorised person(s) on when to approach a potential participant, what information they should provide (written and verbally), and how to record details of the consent decision. Staff at project locations delegated this task should be recorded on the research project delegation log (STU-AD-TMP-019).

For a CTIMP, confirmation of eligibility prior to consent is regarded as a medical decision and must be completed by medically qualified individuals.

4.3 Discussing the research project with a potential participant

Authorised staff at the project location(s) listed on the local delegation log (STU-AD-TMP-019) should approach a potential participant in accordance with the approved protocol and should discuss the research project with them in an unbiased manner using the PIS for information. The privacy and dignity of the potential participant should be taken into consideration and, where possible, a private area sought for discussions that take place.

The potential participant must be informed of their right to withdraw from the research project at any time without the need to give a reason, and without their rights or healthcare being affected. The potential participant should be invited and encouraged to ask questions and given time to consider their response before deciding on whether to agree to take part in the research project.

The protocol should stipulate how long a person has before they are asked to make a consent decision and the potential participant must be made aware of this.

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 number and date of the relevant information sheet, etc. the potential participant has been given
c. the date and time that the information was given to them

When possible, potential participants may allowed extra time to consider participation and offered the option of speaking to an independent person.

4.4 Receiving consent

Only the most recently approved ICF may be used for recording informed consent on paper / electronically.

Authorised staff at research locations should approach the potential participant at an appropriate time and determine whether they wish to participate in the research project or not. The protocol should describe how to record the decision to either decline or accept the invitation to participate. Typically a screening/enrolment log is used.

If the potential participant agrees to take part, they should initial the statements on the ICF as appropriate (some may be optional e.g. informing the participant's GP) and then sign and date the form.

Authorised staff should check that the form has been completed correctly before countersigning and dating 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 participant consented to the project must be recorded in the participant's medical records. This enables a clear audit trail to document that no project specific activities occurred prior to consent being obtained.

4.5 Evidence of consent provided

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

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

The participant's medical records should be updated with the consent decision and the time and date that it was given. A copy of the PIS and signed ICF should also be filed in the medical records and sent to the participants GP if required by the protocol and appropriate consent has been given.

4.6 Seeking Informed Consent by Post

There are some circumstances where it may be appropriate to seek consent from potential participants via letter.

The usual process is to send the approved PIS and ICF in the post. There may be instances when the information will be discussed by a health care professional and taken away the potential participant to return by post. Participants who consent will sign and date the ICF and return it to the appropriate address. An authorised member of the research team will sign the returned consent form once returned and send a completed copy to the participant and document in the health records as described above.

The status of participants who do not respond after an agreed number of reminders have been sent (if appropriate) or who actively decline participation should be updated on the enrolment log to make sure they are not contacted again.

4.7 Seeking Informed 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 participants should be an ongoing process. It is important that ongoing verbal consent is confirmed as part of each research-contact.

When there is a significant change to the research project or the discovery of important new information that may be relevant to the participant's willingness to continue in the project, explicit, written consent must be requested again.

Revised and REC approved PIS and ICF documents must be provided to the participant in a timely manner, recorded in the patient's medical records and any relevant research-specific CRFs.

The participant should be given sufficient time to consider their continued involvement and to ask questions as above, before being asked to sign the revised consent form, which must be kept alongside the original forms.

4.9 Withdrawal of consent

A participant 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 participant agrees to 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 participant via the PIS.

Any data and samples already collected at the time of withdrawal may be retained and used for analysis unless the former participant requests that the information be destroyed. This request must be documented and actioned where possible. There may be legal, regulatory or clinical requirements which would prevent the destruction of CRFs. The participant would be informed of such instances at the point of first consenting to the project and advised that the CRFs will be held under quarantine conditions where possible. If data and/or samples cannot be destroyed for practical reasons, the PIS should make this clear prior to consent being requested. An example of this would be if too many participants dropped out and withdrew their data, making the project unviable.

4.10 Subsequent loss of capacity

If a participant loses their capacity to provide consent during the research project, the original consent decision remains legally valid. However, the participant's legal representative or

family member will be approached to their consent of the participant to continue in the project as per STU-SOP-TM-005. Should they decline the participant continuing in the project, data collected under the original consent documents will remain as project data.

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 2025 - https://www.legislation.gov.uk/uksi/2025/538/contents
- ICH GPR E6 (R3) https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf
- The Clinical Trials Toolkit - http://www.ct-toolkit.ac.uk/routemap/informed-consent/
- HRA and MHRA joint statement on seeking and documenting consent using electronic methods (eConsent) last updated Sept 2018 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	QMS

7. Appendices

Appendix 1: Developing the documentation, process and approvals for seeking and recording informed consent