STU-SOP-TM-008 – Standard Operating Procedure on Informed Consent in a Paediatric Setting

1. Purpose and Definitions

This Standard Operating Procedure (SOP) describes the procedure of obtaining "informed consent" to recruit Children and Young People (CYP) into a research project in the UK. It also includes how a consent decision should be recorded.

Definitions	
Children and Young People	For research purposes, any person under the age of 16 is classified a "minor" and cannot provide informed consent to participate in research. A CYP can give assent if they understand and agree to the research project but a personal or professional legal representative must give their consent before the CYP can be included.
Legal representative	For research purposes, this individual can be known to the CYP (i.e. a close family member) or an independent professional (e.g. medical person not involved in the research project) who will decide whether or not to consent to the CYP participating in the research project. The proposed representative must be legally able to decide on behalf of the CYP.

2. Background

Informed consent must be provided by the legal representative before a CYP 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 CYP and legal representative have been informed about the research project. It should be an ongoing process of information exchange for the duration of the research project.

Assent may be sought from a CYP prior to asking the legal representative to make a consent decision on behalf of the CYP. The process of assent will be necessary if the CYP is able to understand the nature and requirements of the research project.
Research projects may use multiple forms of information such as information sheets, videos, audio, brochures etc.

For a research project, the informed consent process and all material used must be approved by an ethics committee for use.

For Clinical Trials of Investigational Medicinal Products (CTIMPs) consent must be conducted in accordance with the UK regulations. This will usually be by a medically qualified professional trained in the informed consent process unless otherwise agreed with the research project Sponsor.

3. Roles and Responsibilities

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

The **Chief Investigator (CI)** is responsible for all aspects of the research project including that staff recruiting into the research project are aware of how to assent and consent CYP. This responsibility may be delegated to the Principal Investigator (PI) at each site.

The **Principal Investigator** (PI) at each research site is responsible for ensuring that only individuals authorised on the delegation log are able to seek informed assent and consent.

The **Trial Manager** (TM) is responsible for managing the development and approval of the CYP and Legal Representative Information Sheets, the CYP Informed Assent Form (IAF) and the Legal Representative Informed Consent Form (ICF) 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 information sheets with potential participants and their legal representatives, discussing any queries, requesting consent and recording the consent decision usually 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

4.1 Preparation of Information Sheets, Assent Forms and Informed Consent Forms

Advice on developing processes and documentation can be found at the HRA decision tool web page referenced in section 6.

4.1.1 Information sheets

Potential participants and their legal representatives should be given full and accurate information about the research project they are being asked to consider, in a format which is suitable for their age and comprehension.

All materials used must be version controlled, dated, identify the unit or department conducting the research and be localised, as appropriate.

4.1.2 Informed assent form

Informed assent forms (IAFs) should be used in research projects if the approved protocol enables CYP to undertake an assent process.

It may be appropriate for IAFs to ask the CYP to select Yes / No rather than to initial each statement on the form.

For research in very young children, the assent process may not be required. The decision should be made on an individual research project basis.

4.1.3 Informed consent forms

The ICF should be completed by the potential participant's legal representative. The ICF must be initialled, signed and dated by an authorised person entitled to act as the legal representative.

4.2 Training site staff to receive informed consent

Consent can be requested by any authorised member of the research team.

Site staff must be trained by the CI or delegate on when to approach a potential participant and their legal representative, what information they should provide (written and verbally), and how to record details of the assent / consent decision.

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

In emergency research involving CYP, informed consent from the legal representative must be received as per the approved protocol. In such instances, an independent medically qualified individual, who is aware of the protocol, may make the decision to give presumed consent.

4.3 Discussing the research project with a potential participant and/or their legal representatives

Authorised site staff should approach a potential participant and/or their legal representative in accordance with the approved protocol and consent documentation.

The potential participant and their legal representative must be informed of his/her right to withdraw from the research project at any time.

The process of seeking informed consent must be documented in the potential participant's medical records or other source document (as appropriate). As a minimum, the following information should be recorded:

- the research project title and/or acronym
- the version of the information sheet, etc. the potential participant and their legal representative have been given
- the date and time that the information was given to them
- the CYP's assent decision

4.4 Receiving consent

The current approved information sheet, IAF and ICF will be used for recording informed consent.

Authorised site staff should approach the potential participant and/or their legal representative at an appropriate time.

If the CYP agrees to take part, they should be asked to complete the appropriate IAF where appropriate. If they decline, it is not advisable to seek overriding informed consent from the legal representative.

The screening log and relevant Case Report Forms (CRFs) will record the consent decision.

4.5 Evidence of consent provided

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

A copy of the completed IAF and ICF should also be given to the participant and their legal representative where appropriate, either as a photocopy, using carbonated paper or having them sign a second set of forms. A copy of the information sheets 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 information sheets, the IAF (where appropriate) and ICF to the legal representative of the potential participant in the post.

There may be instances when the information will be discussed by a health care professional and taken away for the potential participant and legal representative to complete and return by post. An authorised member of the research team will countersign the returned consent form and send a completed copy to the participant and their legal representative.

The status of potential participants or legal representatives 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 published a joint statement in 2018 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. The statement and applicable guidance/regulations can be found in the HRA joint statement referenced in section 5.

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

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 there is important new information that may be relevant to the participant's willingness to continue in the project, explicit, written consent must be requested again. The participant and their legal representative should be given sufficient time to consider their continued involvement and to ask questions as above, before signing the revised consent form, which must be kept alongside the original forms.

Revised information sheets, IAFs and ICFs must be provided to the participant or legal representative and recorded in the patient's medical records and any relevant research-specific CRFs.

On reaching 16, the participant must provide their own informed consent for the research project for their participation to be valid. The protocol should include information on how this process will happen. The legal representative must be made aware of this process happening.

4.9 Withdrawal of consent

A participant or their legal representative 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.

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. There may be legal, regulatory or clinical requirements which would prevent the destruction of CRFs. The participant or legal representative would be informed of such instances and advised that the CRFs will be held under quarantine conditions.

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

- Involving children in research: MRC and ESRC joint guidance (2021)– https://www.ukri.org/publications/involving-children-in-research-mrc-and-esrc-joint-guidance/
- HRA and MHRA publish joint statement on seeking and documenting consent using electronic methods (eConsent) (2018) – https://www.hra.nhs.uk/about-us/news-updates/hra-and-mhra-publish-joint-statement-seeking-and-documenting-consent-using-electronic-methods-econsent/
- Consent and participant information sheet preparation guidance 2017 – https://www.hra-decisiontools.org.uk/consent/

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	STU-AD-TMP-019	STU-AD-TMP-019

7. Abbreviations

List of Abbreviations	
AD	Associated Documents
CI	Chief Investigator
CRF	Case Report Form
CTIMP	Clinical Trial of an Investigational Medicinal Products
CYP	Child(ren) and Young Person/People
GCP	Good Clinical Practice
IAF	Informed Assent Form
ICH	International Conference on Harmonisation
ICF	Informed Consent Form
ISF	Investigator Site File
HRA	Health Research Authority
MHRA	Medicine and Healthcare Products Regulatory Agency
NHS	National Health Service
PI	Principal Investigator
RN	Research Nurse
SOP	Standard Operating Procedure
STU	Swansea Trials Unit
SU	Swansea University
TM	Trial Manager

8. Appendices

Appendix 1: Document History

Version No:	3	Effective Date:	25-Mar-2024
Description of changes:	Update of reference links Inclusion of updated guidance Moved to SOP template v5		

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