SOP number	**17.055**	Version	**2.0**
Title	**Obtaining Informed Consent and Assent (Children)**		

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SOP category	NHS GG&C Clinical Research Facility – Clinical

Staff category

Staff Category	**R**	**A**	**C**	**I**
Nursing	X			
Administration	X			
Paediatric Principal Investigator	X			
Clinical Research Fellow	X			
GCRF Manager		X		
GCRF Associate Director				X
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1. Scope

This procedure applies to all clinical staff working with children and young people within Glasgow Clinical Research Facility (GCRF).

2. Purpose

The purpose of this SOP is to describe the procedure to be followed when obtaining informed consent and assent from a child, person with parental responsibility (PPR) or legal representative for participation in clinical research. For the purposes of this SOP the term 'child' will be used for a child or young person up to age of 16 years. The specific process for each study will have been approved by the Research Ethics Committee.

Informed consent is the process by which a participant voluntarily confirms their willingness to participate in a particular study having been informed of all aspects of the study that are relevant to their decision to participate and having had the opportunity to consider the information provided. This must be recorded in writing, dated and signed. Neither the investigator nor the investigator site staff should coerce or unduly influence a participant to participate or to continue their participation in the trial.

In writing is defined as typing, printing, lithography, photography or other modes representing or reproducing words in a visible form. The majority of research studies use a paper-based approach with a written, dated and signed consent form. Electronic methods for informing, seeking, confirming and documenting informed consent can also be used in clinical research.

Informed consent must be given by each study participant, PPR or legal representative prior to performing any study specific procedures, tests or treatments which are not considered part of standard care.

Child assent should be obtained, where possible, when consent is not appropriate for reasons of their capacity or when recruiting to a Clinical Trial of a Medicinal Product (CTIMP).

Parental assent should be obtained when a child has been deemed competent to provide their own consent. Although this is not legally required when consent is obtained from a competent child, parental assent may be sought as parental support is usually required for participation in the clinical research. However, when sensitive areas (e.g. sexual health, personal attitudes, and behaviours) are included in the research, the competent child's right to privacy must be respected and parental assent may be omitted.

3. Procedures

3.1. Who

The Principal Investigator (PI) is responsible for the overall management and quality of the informed consent process ensuring informed consent/assent is obtained from all study participants, PPR or legal representatives on the study.

The PI can delegate any or all aspects of the informed consent process to appropriately qualified and trained members of the team as recorded on the delegation log.

Non-medical members of the research team involved in the consent process must be able to demonstrate their competency in this skill. This may be evidenced through completion of a competency framework and/or having completed a relevant informed consent course.

Capacity of a child to provide consent should be assessed by an appropriately trained and experienced healthcare professional. If you are unsure or if there is any dispute, a second opinion should be sought.

For Clinical Trials of Investigational Medicinal Products (CTIMPs) the Medicines for Human Use (Clinical Trials) Regulation 2004 and amendments prohibit children under 16 years from giving consent. A child with capacity can give their assent demonstrating their willingness to participate.

For non-CTIMPs where a child is deemed to have capacity by a qualified healthcare professional, and if documented in approved protocol, then child consent can be obtained, with documented agreement obtained from PPR or legal representative. If the child is deemed not to have capacity, then consent should be obtained from the PPR or legal representative, with assent obtained from the child, if appropriate.

3.2. How

3.2.1. Providing information to potential participants

The written Participant Information Sheet (PIS) must be approved by a Research Ethics Committee and printed on local headed paper. The information in the PIS will be consistent with the protocol and will inform the potential participant of the nature, significance,

implications and risks of taking part in the research study. The PIS should be available in age specific formats as appropriate for each research study.

The term Participant Information Sheet includes materials that are provided in electronic formats.

Potential research participants and PPR or legal representative must be provided with participant information, both verbally and written. The potential participant, PPR or legal representative must be given time to read the PIS (as defined in the REC application or protocol), and the opportunity to ask questions and discuss the research study with a member of the research team.

The version number, date and time the information is provided, and by whom, must be recorded in the participant health records.

3.2.2. Receiving paper-based written informed consent/assent

Only members of the research team identified in the study delegation log can obtain informed consent/assent from participants and person with PPR or legal representative responsibility.

The team member receiving informed consent must ensure the participant and PPR or legal representative fully understands what they are consenting to, confirming each statement on the consent form with the participant/PPR, and that they are under no obligation to participate and that they can withdraw at any time, with no impact to their care and treatment. The investigator should be assured of the identity of the participant (or legally acceptable representative).

The participant, PPR or legal representative should personally initial the box next to each statement (if included on the form), print their name, sign and date the informed consent form in ink. Statements not consented to by the participant should be managed as defined in the study specific protocol/SOP. The PI or delegated team member must then sign and date the informed consent form.

Once all parties have signed the informed consent form the person obtaining consent must quality control check all boxes have been initialled and signed appropriately, any corrections must be initialled and dated. Participants/PPR/legal representative must ensure their initials match their signature. The participant/PPR/legal representative must receive a copy, together with a PIS and study contacts details. The original copy of the signed consent form must be filed in the Investigator Site File and a copy of the signed consent form must be uploaded to the participant's health records.

A record of the informed consent process must be recorded in the participant's health record following SOP 57.005.

3.2.3. Participants Unable to read and/or write

If a participant (providing consent for themselves), PRR or legal representative is unable to read, an impartial witness should be present during the entire informed consent discussion.

The Participant Information Sheet and Consent form must be read and explained to the participant by the person receiving consent.
If the participant, PRR or legal representative orally consents to the participant's trial participation and, if capable of doing so, have signed and dated the informed consent form, the witness should sign and date the consent form. By signing the consent form, the witness attests that the consent information was accurately explained to and apparently understood by the participant and that informed consent was freely given by the participant.

3.2.4. Remote Consent

The purpose of remote consent is to allow the research team and potential participant/PPR/legal representative to engage in the informed consent process in a way that is similar to what would be conducted in-person.

Where remote consent has been agreed by the study sponsor please follow Guideline 17.012A.

3.2.5. Electronic methods for seeking, confirming and documenting informed consent

The key elements of the informed consent process remain unchanged when using electronic methods. The potential participants/PPR/legal representative need to be informed of the research study, provided the opportunity to ask questions and discuss the study with a member of the research team.

This process may be completed without any contact (e.g. using electronic recording of process) or with minimal contact using surfaces that are readily cleaned (e.g. hand-held devices).

When using an electronic signature these are classed as 'simple', 'advanced' or 'qualified'. The type of electronic signature, will be defined in the protocol and will depend on whether the recruitment and consent process taken as a whole mean that you can:

- Trust that the person who signed is who they say they are
- Trust that the consent form signed hasn't been altered
- Trust when signature was applied
- Demonstrate that trust if required. (Health Research Authority & Medicines and Healthcare Products Regulatory Agency (2018) Joint statement on seeking consent by electronic methods.)

A PDF of the signed electronic consent form must be provided to the participant/PPR/legal representative and a copy scanned to participant's heath record. The method of capturing the signature should be proportionate to the risk of identity fraud.

Electronic methods of consent can either supplement the traditional paper-based approach or, where approved and appropriate, as a replacement. The Health Research Authority & Medicines and Healthcare Products Regulatory Agency (2018) Joint statement on seeking consent by electronic methods states that 'you should use the format best suited to the nature of the information that needs to be provided to potential participants, and which best supports their understanding of it'.

3.2.6. Ongoing consent process during the study

Informed consent is an ongoing process that continues after the informed consent form has been signed. At each study visit the research team must re-confirm and document in the health records the participant, PPR or legal representative wishes to continue in the study, following SOP 57.005.

The child should also give assent on age specific assent forms as they mature throughout the study. (e.g. when a child recruited at 9 years reaches 10 years, and there is a 10-16 year PIS and consent/assent form, the child should be re-assented at age 10). However the capacity of the child must be considered, especially for neuro atypical children or those with cognitive delay. Any decision regarding this should be recorded in source document and if appropriate consider a file-note. When re-consenting is required the procedure in section 3.2 must be followed.

If a child becomes 16 years old during the trial, and are deemed competent, they must be consented using the appropriate consent form.

Where there is a wish to withdraw participation from a study the date, time and where available the reason for withdrawal should be documented in the health records. Following study protocol, relevant study specific documents must also be completed.

3.2.7. Modifications

Where changes to the trial design, medication or risks are approved as modifications the sponsor may require participants/PPR/legal representative to be re-consented. When re-consenting is required the procedure in section 3.2 must be followed.

3.2.8. Deferred Consent of a Child in Emergency Research

3.2.8.1 CTIMPs

The provision for consent in Emergency Research is defined in Amendment 3 Medicines for Human Use (Clinical Trials) Regulations SI 2008: 941.

A child can be recruited into a CTIMP in an emergency situation and can be administered a treatment without prior written consent as a matter of urgency and, having regard to the nature of the clinical trial and the particular circumstances of the case only when:

- It is necessary to recruit the patient and hence administer treatment within the clinical trial as a matter of urgency and it is not reasonably practical or ethical to obtain informed consent prior to entering the participant.
- The action is carried out in accordance with a procedure given a favourable opinion by a Research Ethics Committee.
- Consent is sought from a person with parental responsibility or legal representative as soon as possible, and as defined in the approved study protocol.

Depending on the circumstances this may be limited information at the time with a verbal agreement, with provision of the full parent/patient information and written

informed consent taken as soon as it is practical and ethical to do so. Or it may be fully deferred consent with no information provided at the time of entering the patient into the study, with provision of the full parent/patient information and written informed consent taken as soon as it is practical and ethical to do so. This will be detailed in the protocol and have ethical approval.

3.2.8.2. Non-CTIMPS

The involvement of children in research for non-CTIMPs without prior consent in emergency situations would be considered ethical if:

- It is not possible to address the same research question by recruiting from a non-emergency environment
- The research is of potential benefit to the child themselves
- Someone with parental responsibility for the child is informed about the research as soon as possible
- Consent (and assent) is sought as soon as possible
- NHS Research Ethics have approved deferred consent for that study
- It is made clear to the child or PPR (if the child is not competent) that the child can withdraw (or be withdrawn by their PPR/legal representative) at any time without penalty.

3.2.9. Transfer of participants previously recruited at alternative trial location

Evidence of Informed consent from the original trial location is required. The Principal Investigator will assess the requirement for reconsent at the new trial location. If reconsent is not sought, this decision must be documented and participant provided with an updated copy of the localised PIS for their new trial location.

4. Referenced documents

- Medicines for Human Use (Clinical Trials) Regulation 2004 SI 1031. as amended by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025
- Amendment 3 Medicines for Human Use (Clinical Trials) Regulations SI 2008: 941.
- Health Research Authority & Medicines and Healthcare Products Regulatory Agency (2018) Joint statement on seeking consent by electronic methods.
- Guideline 17.012A - Remote consent
- SOP 57.005 - Hosted Study Documentation and Data Management

5. Related documents

- Children (Scotland) Act 1995
- Parental Responsibilities and Rights: Scottish Government
- Medicines and Healthcare Products Regulatory Agency (2012) Guide to Good Clinical Practice, The Stationary Office, London.
- International Conference on Harmonisation (2025) Harmonised Tripartite Guideline for Good Clinical Practice.
- UK Policy Framework for Health and Social Care Research (2017)
- Medicines for Human Use (Clinical Trials) Regulations 2004 ("the Clinical Trials Regulations"), as amended by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025

- World Medical Association. (2024). Declaration of Helsinki: Ethical principles for medical research involving human participants.

6. Document history

Version	Date	Description	Retrospective Implementation
1.0	03/02/2023	First release	No
2.0	11/11/2026	Transferred to new R&I SOP template V1 Change of author and released by Minor modifications to wording. Clarifications made in relation to ICH R3 Addition of guidance for participants transferring between sites. Addition of guidance for participants unable to read/write	No

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