Standard Operating Procedure			**17.055**
Obtaining Informed Consent and Assent (Children)			
Version	**1.0**		
Prepared by	Naomi Hickey	Signature	Date
Approved by	Lynn Prentice	Signature	Date
Released by	Julie Brittenden	Signature	Date

1. SOP Category
NHS GG&C Clinical Research Facility – Clinical

2. Staff Category

Staff Category	R	A	C	I
GCRF Nursing (Paediatric)	X			
GCRF Principal Investigators and study teams	X			
GCRF Management Team		X		

3. Scope
This procedure applies to all clinical staff within Glasgow Clinical Research Facility (GCRF).

4. 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 subject 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, had the opportunity to consider the information provided and must be recorded in writing, dated and signed. 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 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 competence or it is 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, behaviours) are included in the research, the competent child's right to privacy must be respected and parental assent omitted.

5. Procedures

5.1. 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 assessed as competent by the PI or designee prior to being delegated the task and if appropriate complete the Informed Consent workshop.

Competency of a child must be assessed by a medical practitioner. After competency has been determined, the process of obtaining informed consent can be delegated by the Principal Investigator to an appropriately qualified and trained member of the research team.

For Clinical Trials of Investigational Medicinal Products (CTIMPs) the Medicines for Human Use (Clinical Trials) Regulation 2004 and amendments prohibits children under 16 years from giving consent. A competent child can provide assent.

For non- CTIMPs where a child is deemed competent by a qualified medical professional, and documented in approved protocol, then child consent can be obtained, with assent obtained from PPR or legal representative. If the child is deemed non-competent by a qualified medical professional then consent should be obtained from the PPR or legal representative, with assent obtained from the child, if appropriate.

5.2. How

5.2.1. 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.

5.2.2. 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 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 initialed and signed appropriately, any corrections must be initialed 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.

5.2.3. 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.

5.2.4. 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 more 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 that should be used in a study depends 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.

Electronic methods of consent can either supplement the traditional paper-based approach or, where approved and appropriate, as a replacement.

5.2.5. 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 grow 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). When re-consenting is required the procedure in section 5.2 must be followed.

If a child becomes 16years 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.

5.2.6. Amendments

Where changes to the trial design, medication or risks are approved as amendments the sponsor may require participants/PPR/legal representative to be re-consented. When re-consenting is required the procedure in section 5.2 must be followed.

5.2.7. Deferred Consent of a Child in Emergency Research

5.2.7.1. **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 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 take action for the purposes of clinical trial as a matter of urgency; but
- It is not reasonably practical to obtain informed consent prior to entering the participant.
- The action is carried out in accordance with a procedure given a favorable 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.

5.2.7.2. **Non-CTIMPS**

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

- First obtain NHS Research Ethics Committee approval
- Cannot address the same research question by recruiting from a non-emergency environment
- 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
- Make 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.

6. Referenced documents

- Medicines for Human Use (Clinical Trials) Regulation 2004 SI 1031.
- 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

7. 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 (2016) Harmonised Tripartite Guideline for Good Clinical Practice.
- UK Policy Framework for Health and Social Care Research (2017)

8. Document History

Version	Date	Description
1.0	03/02/2023	Creation of SOP