SOP number	**17.012**	Version	**7.0**
Title	**Obtaining Informed Consent (Adults)**		

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SOP category	17. NHSGGC Clinical Research Facility – Clinical

Staff category

Staff Category	**R**	**A**	**C**	**I**
Education & Quality Lead		X		
Nursing	X			
Administration	X			
Principal Investigator	X			
Clinical Research Fellow	X			
GCRF Manager		X		
GCRF Associate Director				X
Senior R&I Manager				X

1. Scope

This procedure applies to all clinical staff 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 of adults in clinical research from a study participant or legal representative. SOP 17.055 must be followed when obtaining paediatric informed consent. 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, had the opportunity to consider the information provided and 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. You can use electronic methods for informing, seeking, confirming and documenting informed consent in clinical research.

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

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 is obtained from all study participants 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. Specific sponsor or protocol requirements should be followed if applicable.

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 Informed Consent training.

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 term Participant Information Sheet includes materials that are provided in electronic formats.
Potential research participants must be provided with participant information, both verbally and written. The potential participant must be given time to read the PIS (as defined in the REC application), 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

Only members of the research team identified in the study delegation log can obtain informed consent from participants.

The team member receiving informed consent must ensure the participant fully understands what they are consenting to, confirming each statement on the consent form with the participant, 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 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 must ensure their initials match their signature. The participant 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 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 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 to engage in the informed consent process in a way that is similar to what would be conducted in-person. The investigator should be assured of the identity of the participant (or legally acceptable representative).

Where remote consent has been agreed by the study sponsor please follow Guidance 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 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.

The type of electronic signature that should be used in a study should be agreed with the sponsor, and depends on whether the recruitment and consent process taken as a whole means 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 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.

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 wishes to continue in the study, following SOP 57.005

Participants who wish to withdraw from a study should have the date, time and where available the reason for withdrawal documented in the health records. Where appropriate, the specific study procedures the participant has withdrawn from should also be noted (for example long term follow up, data storage etc). 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 to be re-consented.

3.2.8. Adults with Incapacity

The inclusion of adults with incapacity into research studies is given special protection, governed by the Adults with Incapacity (Scotland) Act 2000 and Medicines for Human Use (Clinical Trials) Regulation 2004 SI 1031. Potential participants who are incapable of providing informed consent should not be included in research studies if the same results can be obtained using persons capable of giving informed consent.

The investigator and delegated members of the research team are responsible for assessing the decision making capacity of potential participants over 16 years of age. The capacity assessment must be recorded in the participant's health records.

Where approved by a Research Ethics Committee, if an adult is assessed as being incapable of providing informed consent a legal representative must be approached to consent on behalf of the participant. A legal representative can be:

- Guardian or welfare attorney who has power to consent to the adult's participation in research, or
- If there is no guardian or welfare attorney, the adults nearest relative; or
- The doctor primarily responsible for the medical treatment provided to the adult or a person nominated by the relevant health care provider (SI 1031 & Adults with Incapacity (Scotland) Act 2000).

When seeking consent from a legal representative the process in section 5.2.2 must be followed and in addition the research team member must:

- Ensure the participant has received information according to their capacity of understanding.
- Consider the explicit wish of the participant capable of forming an opinion and assessing the information provided.
- Consider the balance of risk versus benefit to the potential participant.

Should a participant gain capacity consent should be sought as defined in the study protocol.

If a capable adult gives informed consent and then subsequently loses capacity with regard to decision making, then the consent remains valid.

If a capable adult refuses informed consent and then subsequently loses capacity with regard to decision making, then the refusal to consent previously remains valid and consent cannot be sought from a legal representative.

3.2.9. Consent of Adult with Incapacity in Emergency Research

3.2.9.1. CTIMPS

An unconscious patient or incapacitated adult 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 favourable opinion by a Research Ethics Committee.
- The participant's legal representative should be informed about the trial as soon as possible, and consent as appropriate should be requested. Should the participant gain capacity, consent should be obtained as defined in the study protocol.

3.2.9.2. Non-CTIMPS

There is no provision to recruit and consent adults with incapacity to non-CTIMP Emergency Research.

3.2.10 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

- SOP 17.055 – Obtaining Informed Consent (Children).
- Adults with Incapacity (Scotland) Act 2000.
- Medicines for Human Use (Clinical Trials) Regulation 2004 SI 1031.
- Amendment 2 Medicines for Human Use (Clinical Trials) Regulations SI 2006: 2984.

- Health Research Authority & Medicines and Healthcare Products Regulatory Agency (2018) Joint statement on seeking consent by electronic methods.
- Guidance 17.012A: Remote consent.
- SOP 57.005: Hosted Study Documentation and Data Management.

5. Related documents

- Medicines and Healthcare Products Regulatory Agency (2012) Guide to Good Clinical Practice, The Stationary Office, London.
- EU Directive 2001/20/EC & Good Clinical Practice Directive 2005/28/EC.
- International Conference on Harmonisation (1996) Harmonised Tripartite Guideline for Good Clinical Practice.
- Scottish Executive Health Department (2006) Research Governance Framework for Health and Community Care, Second Edition, Edinburgh.

6. Document history

Version	Date	Description	Retrospective Implementation
Draft	12/10/07	Creation of SOP	No
1.0	22/11/07	Release of Version 1 (for review)	No
1.1	19/05/08	Released to staff	No
2.0	27/08/14	Major changes to clarify the responsibilities of the research team receiving informed consent. The purpose and process for receiving consent has been expanded to include the process when re-consenting is required and the process for Adults with Incapacity participating in Research.	No
3.0	15/07/16	SOP restructure Minor admin changes Change to approved and released by	No
4.0	26/08/2019	Periodic review and minor changes	No
5.0	05/05/2021	Changes to reflect remote consent, seeking and recording consent using electronic methods, and use of electronic signatures.	No
6.0	28/09/2022	Removal of consent process documented in electronic health record (detailed in SOP 57.005) Addition of SOP 17.055 – Obtaining Informed Consent (Paediatrics) Addition of SOP 57.005	No
7.0	05/01/2026	Transfer to SOP updated template Change to author and released by Addition of RACI matrix Addition of consent for participants transferring between locations	No