SOP number	**51.002**	Version	**6.0**
Title	**Participant Information Sheet and Informed Consent Form Development for Research Sponsored by NHSGGC or Co-Sponsored by NHSGGC and the University of Glasgow**		

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SOP category	NHSGGC Sponsor R&I

Staff category

Staff Category	**R**	**A**	**C**	**I**
Systems & Operations Manager		X		
Chief Investigator	X			
Project Management	X			
Sponsor Research Co-ordinators	X			
Sponsor Research Facilitator	X			
Innovation Project Manager	X			
R&I Sponsor Pharmacy	X			
Innovation Contracts Manager			X	
R&I Pharmacovigilance			X	
University of Glasgow Research Regulation and Compliance team			X	
R&I Clinical Trial Monitors			X	
Senior Research Administrators			X	

1. Scope

This SOP applies to R&I staff listed above and specific experts as required during the development and review of study-specific participant documentation for Clinical Trials of Investigational Medicinal Products (CTIMPs), Clinical Investigations of Medical Devices (CIMDs) and all other research studies involving humans, their tissues and/or data (together referred to as 'research studies') which are Sponsored by NHS Greater Glasgow and Clyde (NHSGGC) or Co-Sponsored by NHSGGC and the University of Glasgow (UoG).

2. Purpose

The purpose of this SOP is to outline the process for designing a Participant Information Sheet (PIS) and Informed Consent Form (ICF) to Good Clinical Practice (GCP) standards to comply with The Medicines for Human Use (Clinical Trials) Regulations 2004 (and amendments), UK Policy Framework for Health and Social Care Research, General Data Protection Regulation (GDPR), Data protection Act 2018 and other relevant legislation.

3. Procedures

3.1. Background

Informed consent is a voluntary and legally binding agreement where a participant or their legal representative agrees to participate in research or treatment after being fully informed about the details, risks, and benefits involved. It is essential that research participants understand fully what is involved and how any information obtained from the research that relates to them, will be used and stored for potential future use and their rights to withdraw from study participation. Consent must never be considered to be implied and can be given in written form, or verbally in exceptional circumstances. These principles should be applied equally to patients and healthy volunteers participating in research studies.

3.2. Responsibilities

The CI is responsible for developing the PIS and ICF. Help with the design of the PIS and ICF is one of the support services offered by the R&I department and is also one of the Board's Sponsor responsibilities. If required, the Sponsor Research Co-ordinator (SRC), Innovation Contract Manager (ICM) or Sponsor Research Facilitator (SRF) (collectively referred to as the R&I Co-ordinator) can support the Chief Investigator (CI) by directing them to resources such as the Health Research Authority (HRA) guidance on PISs and ICFs, providing example documents, sharing the PIS and ICF guidelines (GUI 51.002A) which includes suggested content and wording, and advising on the minimum content requirements for studies sponsored by NHSGGC, as outlined in this SOP.

For Project Manager (PM) supported studies developing the PIS and ICF is usually done in conjunction with the wider Trial Management Group (TMG). The R&I Co-ordinator is responsible for review and approval of the PIS and ICF in line with this SOP. The CI or PM is then responsible for submitting these documents to the REC (as per SOP 51.014). Review of the content and suitability of a PIS and ICF is the remit of the REC.

3.3. Design of a PIS

A PIS is a formalised and approved document that is intended to provide trial participants with a definitive and comprehensive description of the research project in which they are being invited to participate. When designing a PIS the following should be considered:

- **Reading age and comprehension** of study participants as the PIS must be understandable in terms of language and content and whether it may be necessary to provide different versions of the PIS to suit different age or comprehension groups.
- Review by a similar (non-study) patient group to ensure understanding of the contents and to highlight any areas of concern, **Patient and Public Involvement (PPI)** in trial and documentation design is strongly recommended (see section 3.5).
- Describe clearly what **potential participants should expect** e.g. number of visits, which locations, length of visits, can they be accompanied and will they receive travel expenses.
- Use of **flow diagrams, pictures or other forms of media** can bring more clarity to the information provided.
- Each iteration of the PIS must be appropriately **version controlled and dated** to ensure identification of it as a different version to that used previously as per SOP 50.017.

- HRA's **transparent wording** or similar must be used, with a link to NHSGGC's Privacy Policy to explain how the participant's information will be used as detailed in GUI 51.002A.
- No language should be used that causes, or appears to cause the participant or their representative to **waive any rights** or release the NHSGGC or the investigator from liability.
- An additional **summary PIS** providing brief information is also recommended for complex studies so that potential participants can access the level of information they wish.

The HRA website provides guidance on the specific topics that must be included e.g. that this is a research study, which elements are experimental, participation is voluntary etc. Section 2.8.10 of ICH GCP E6 (R3) also gives guidance on areas of consideration to be included in any PIS. In addition, GUI 51.002A also provides guidance on suggested content and wording which can be tailored depending on the specific type of study.

3.4. Design of an ICF

When designing an ICF the following must be considered:

- The ability of study participants to identify and weigh up **benefit and risk** and make a decision based on the information given
- Consideration must be given to the current versions of the Adults with Incapacity (Scotland) Act and the Mental Capacity Act (England, Northern Ireland and Wales) and regarding participants who are permanently or temporarily **mentally incapacitated** (see section 3.8.)
- If the participant is a **child** who is capable of understanding the PIS and can make an informed decision about participation then consideration to the age of the child, their understanding of the treatment and/or intervention should be taken into consideration (see section 3.7.)
- If **electronic consent** is considered, a paper format must always be offered as an alternative if preferred by participant (according to ICH GCP R3 – 2.8.1)
- Participants must specifically consent to their samples being subject to **DNA analysis** and their samples being used in conjunction with **animal products**
- All **optional consent items** must be at the end of the form and include yes / no boxes for initials to indicate choice e.g. contribution to future research studies
- Section for **witness signature** must also be added, only to be completed in the event a participant is able to consent but has a physical disability that would prevent them physically signing
- **File instructions** must be added at the end of the document, e.g. 1 copy for patient, 1 copy for medical notes, original copy to be filed in the Investigator Site File (ISF) (see section 3.10.)

The HRA website provides guidance on the specific headings and statements that must be included i.e. the title of Informed Consent, the research study title and protocol ID, the various statements that must be initialled by the participant, the identification of the investigator and study location and the signature section. In addition, GUI 51.002A also provides guidance on suggested content and wording which can be tailored depending on the specific type of study.

3.5. Patient and Public Involvement (PPI)

Patient and Public Involvement (PPI) refers to the active collaboration of patients, carers, and members of the public in the planning, design, conduct and dissemination of research. PPI ensures that research is relevant, accessible, and focused on participant needs. Many research funders require PPI as part of funding applications and RECs increasingly expect evidence of PPI. If the CI requires support with PPI in designing the PIS and ICF, the R&I Co-ordinator can connect them with appropriate contacts within both the UoG and NHSGGC. These contacts can help coordinate relevant groups to contribute effectively to the development of the PIS and ICF.

3.6. Research Involving Participants with Language, Written and Oral Communication or Comprehension Difficulties

Adults must be presumed capable of making decisions unless the opposite has been demonstrated. Where there are comprehension or communication difficulties then participants must be given all appropriate help to enable them to make their own decisions e.g. using visual aids, sign language etc.

Where there are communication or comprehension difficulties, two types of PIS may be required: one for a relative or an independent participant's advocate and one for the participant. The latter should be designed to overcome or minimize some of the communication problems, for example, a pictorial PIS for the participant.

Where there are difficulties with writing and the participant has the capacity to consent but cannot write due to their illness or disability, a witness may sign on behalf of the participant as detailed in section 3.10.

Where there is a language barrier involved, the CI and R&I Co-ordinator for each study will be responsible for determining if translated written material is to be provided to participants, and if they will be provided by the Sponsor, or translated locally, based on patient population and available funding. Where possible, for CTIMPs, Sponsor will translate all patient facing documents, including PIS and ICF, into most prevalent languages in the study population and provide to study locations ahead of study opening to recruitment and at each subsequent modification. A translator, who must be independent of the participant and the study team, must also be available for discussion with the potential participant and PI (or delegate) taking consent as per local process. Details of the interaction between the translator and the patient, including the name of the official translator, must be documented in the patients' medical notes at each visit. This will include translation of Pharmacy dispensing advice of study medications. Continued consent should also be ensured when language barriers are involved by the provision of translators at appropriate time points.

3.7. Research Involving Paediatric Participants

Relevant information must be provided in age appropriate written or pictorial form and the roles and responsibilities of parents or guardians, carers or supporters must be clearly explained and understood. The types of ICFs and assent forms which may be required differ depending on the type of study and where it is taking place, some examples are listed in the table below.

Paediatric consent in England and Scotland for CTIMPs	• **Under 16:** participants require parent/guardian to provide consent and participant can provide assent. • **16+:** participant provides consent and parents can provide assent **Legislation:** The Medicines for Human Use (Clinical Trials) Regulations 2004
Paediatric consent in Scotland for non-CTIMPs	There is no specific provision in Scots law governing a child's right to consent to take part in research. Common law assumes: • **Under 12:** Parents provide consent and child can provide assent • **12-16:** Participant can provide consent if child deemed to have capacity and parents provide assent. If not, parents provide consent and child can provide assent. • **16+:** Participant provides consent and parents can provide assent. Principles of consent: Children and Young People (Scotland) - Consent and Participant information sheet preparation guidance. (hra-decisiontools.org.uk)
Paediatric consent in England for non-CTIMP	There is no specific law in England, Wales or Northern Ireland governing a child's right to consent to take part in research other than a CTIMP. Common law assumes: • **Under 16**: Parents provide consent and participant can provide assent • **16-18:** participant can provide consent if deemed to have capacity and parents can provide assent. If not, parents provide consent and participant can provide assent. • **18+:** Participant provides consent. Research involving children - Health Research Authority (hra.nhs.uk)

3.8. Research Involving Adults Lacking Capacity (ALC)

An adult lacking capacity (ALC) is defined under the Medicines for Human Use Clinical Trials Regulations 2004 as "an adult unable by virtue of physical or mental incapacity to give informed consent". ALC may still be included as participants in a clinical trial where there are grounds for expecting that administering the intervention or medicinal product to be tested will produce a benefit for the participant. It is possible in the research setting for a third party to act in the incapacitated patient's best interest with regards to participating in research. These participants fall under different legislation across the UK and different third party PISs/ICFs are required as detailed in the table below. In addition, UK-wide research projects including involving ALC must navigate ethics approvals across jurisdictions to ensure compliance with local laws and ethical standards as detailed in section 3.8.1.

Scotland: Adults Lacking Capacity for CTIMPs	• **Consent** can be provided by:
	  ○ **Personal legal representative** i.e. A **welfare guardian** or **welfare attorney** (if appointed), or **nearest relative with authority** under the Act, or from a **named person** if appointed under the Act.
	  ○ If no guardian/attorney is appointed, a **proxy** may provide consent, but only after certain safeguards are met, such as the involvement of an independent medical practitioner and adherence to the specific research ethics frameworks.
	
	• **Ethics review coordination**: Centralised UK-wide process but local REC opinions required (see section 3.8.1)
	
	Legislation: Adults with Incapacity (Scotland) Act 2000 (legislation.gov.uk), The Medicines for Human Use (Clinical Trials) Regulations 2004

England and Wales: Adults Lacking Capacity for CTIMPs	• **Consent**: provided by a legal representative, a person who can act on behalf of the adult lacking capacity, such as:
	  ○ A **personal legal representative** (family member or someone close to the participant who is not connected with the conduct of the trial and willing and able to decide).
	  ○ If no personal legal representative is available, a **professional legal representative** (doctor or other healthcare professional not connected to the trial).
	
	• **Ethics review coordination**: Centralised UK-wide process but local REC opinions required (see section 3.8.1)
	
	Legislation: Mental Capacity Act 2005 (legislation.gov.uk), The Medicines for Human Use (Clinical Trials) Regulations 2004

Scotland: Adults Lacking Capacity for non-CTIMPs	• **Consent** can be provided by:
	  ○ A **welfare guardian** or **welfare attorney** (if appointed), or **nearest relative with authority** under the Act, or from a **named person** if appointed under the Act.
	  ○ If no guardian/attorney is appointed: a **proxy** may provide consent, but only after certain safeguards are met, such as the involvement of an independent medical practitioner and adherence to the specific research ethics frameworks.
	
	• **Ethics review coordination**: Separate local REC reviews for ALC documentation per jurisdiction (see section 3.8.1)
	
	Legislation: Mental Capacity Act 2005 (legislation.gov.uk), UK Policy Framework for Health and Social Care Research - Health Research Authority

England and Wales: Adults Lacking Capacity for non-CTIMPs	• **Consent:** obtained via a **consultee** (someone who advises on whether the person would have wanted to participate, but does not legally give consent on behalf of the person. The actual consent is "consent by proxy," based on the consultee's advice). • **Ethics review coordination**: Separate local REC reviews for ALC documentation per jurisdiction (see section 3.8.1) **Legislation:** Mental Capacity Act 2005 (legislation.gov.uk), UK Policy Framework for Health and Social Care Research - Health Research Authority

3.8.1. REC review process for ALC paperwork

CTIMPs have a centralised UK-wide submission and approval process that includes ethics review by the relevant RECs and HRA in England. Non-CTIMPs however, must be submitted and approved separately to the appropriate RECs.

Scotland: A REC may receive the ALC paperwork as part of a main ethics application that covers the whole UK. However, they do not:

- Review the ALC documents for study locations outside Scotland.
- Issue an ethical opinion on those ALC materials if they relate to participants or study activities in England or Wales.
- Include ALC documents in their final list of approved documents when these relate to England or Wales.

To include ALC participants in England or Wales, a second review by a REC based in England or Wales is mandatory. This second REC:

- Receives the full UK-wide paperwork, including the ALC documents
- Conducts a formal review of the ALC aspects relevant to England/Wales
- Issues a separate ethical opinion specific to those locations.

The same process would apply in reverse for ALC documentation if the main REC is in England or Wales.

3.8.2. Participants Who Regain Capacity

If it is possible participants might regain capacity during the course of a study, there must be provision made for the on-going consent process. In most cases it is appropriate to ask patients to give their own consent when/if they are able. An approved PIS and ICF for participants who regain capacity must be used and the process detailed the study protocol and the REC submission documents.

3.8.3. ALC in Emergency Research

Emergency research is when treatment needs to be given urgently, and it is necessary to take urgent action for the purposes of the study.

In some emergency situations:

- Potential participants may lack capacity to give consent themselves, and
- Obtaining consent from a legal representative / consulting others is not reasonably practicable.

In these cases, participant enrolment without prior consent is permitted depending on the type of study and the jurisdiction as detailed in the table below.

Scotland: emergency research without prior consent for CTIMPs	• In Scotland, CTIMPs may include adults lacking capacity without prior consent in emergency situations if all of the following are true:
	  ○ The treatment needs to be administered urgently.
	  ○ It is necessary to act urgently to administer the IMP for research purposes.
	  ○ It is not reasonably practicable to obtain consent from a legal representative in time.
	  ○ The study is approved by an NHS Research Ethics Committee.
	• Consent must be sought from a legal representative **as soon as possible** after enrolment.
	
	Legislation: Adults with Incapacity (Scotland) Act 2000 (legislation.gov.uk), The Medicines for Human Use (Clinical Trials) Regulations 2004

England and Wales: emergency research without prior consent for CTIMPs	• In emergency situations, the law in England allows adults lacking capacity to be recruited into CTIMPs without prior consent, provided all of the following conditions are met:
	  ○ The treatment must be given urgently.
	  ○ It is also necessary to take urgent action to administer the investigational medicinal product (IMP) for the purposes of the trial.
	  ○ It is not reasonably practicable to obtain consent from a legal representative before enrolment.
	  ○ The procedure has been approved by an NHS Research Ethics Committee.
	• Consent must be sought from a legal representative **as soon as possible** after enrolment.
	
	Legislation: Mental Capacity Act 2005 (legislation.gov.uk), The Medicines for Human Use (Clinical Trials) Regulations 2004

Scotland: emergency research without prior consent for non-CTIMPs	• **Consent must be in place before participation can begin.** • There are no legal exemptions for emergency inclusion without consent in non-CTIMP research. **Legislation:** Adults with Incapacity (Scotland) Act 2000 (legislation.gov.uk), UK Policy Framework for Health and Social Care Research - Health Research Authority
England and Wales: emergency research without prior consent for non-CTIMPs	• In certain circumstances, recruitment without prior consent may still be possible, but the situation is less clearly defined than for CTIMPs. • Ethical and legal advice is recommended to assess whether the research is permissible. **Legislation:** Mental Capacity Act 2005 (legislation.gov.uk), UK Policy Framework for Health and Social Care Research - Health Research Authority

3.9. Which staff groups can receive consent?

The delegation of the responsibility for taking Informed Consent process for each staff group will be decided on a trial-by-trial basis. This will be confirmed at trial set-up with the R&I Co-ordinator and will be detailed clearly in the protocol and REC submission documents as per SOP 51.014. Staff taking consent must be trained in consent taking and on the delegation log, this is a study location's responsibility to ensure. Consent must always be freely given after the participant or their representative have been given sufficient detail to make an informed decision on participation in a trial except for some emergency settings. Staff taking consent must never coerce or unduly influence this decision.

3.10. Recording and Documenting Consent

Consent must never be implied and can be given verbally and in written form. Verbal consent should only be taken if this is specified in the study protocol and agreed by the relevant REC in advance. All boxes must be initialled (including optional consent boxes), signed and dated by the participant (or legal representative) and the PI (or delegate) for the ICF to be valid. A witness may sign on behalf of the participant, only if the patient has capacity to consent but cannot write due to their illness or disability. The witness must witness the PI (or delegate) giving the PIS to the patient and explaining the study with sufficient time to consider. Verbal consent from the patient will be given to the person taking consent and the witness. The witness must then complete the ICF on the patient's behalf, initial the relevant boxes with their own initials, and sign the ICF as a witness. The arrangements for consent must be described clearly in the REC submission documents as per SOP 51.014. In all instances, the staff taking consent must assure themselves of the identity of the individual, and where applicable representative, they are taking consent for.

Wherever possible a written record of consent must be obtained. If appropriate, the ICF should be uploaded to the eCRF to allow for remote monitoring. The original ICF must be filed in the Investigator Site File (ISF). A copy of the signed ICF must be given to the participant and, if appropriate, a copy filed in their medical notes. A description of the consent process and discussion should also be documented in the patient's medical notes where appropriate. Healthy volunteer studies only require a copy to be given to the participant and a copy held in the study file.

3.10.1. Remote Consent

If it is appropriate to consent remotely, this will be fully described in the study protocol and REC submission documents as per SOP 51.001 and SOP 51.014. This will be decided and agreed by Sponsor representatives before a study is opened to recruitment or after a modification. The participant will be sent all necessary trial documentation electronically or via post (including PIS and ICF) and given sufficient time to consider these before the discussion. The PI or appropriately trained delegate will then conduct a discussion via video call or telephone call. A minimum of 2 identifiers must be used to confirm identity of participant (e.g. name and date of birth). In all cases of remote consent, full and detailed documentation of the process including names of all personnel involved must be recorded in the source documentation. For an interventional study, written consent must take place prior to intervention.

3.11. Amending PIS/ICF

All changes to a previously approved PIS or ICF must be submitted as a modification in accordance with SOP 51.021 before implementation, unless delaying the change would harm the participant. Substantial modifications, such as those affecting study design, participant safety, or the consent process, must be submitted to the appropriate review bodies, including the REC.

If a modification alters the risk–benefit ratio or alters study procedures in a way that may impact a participant's decision to continue, re-consent will be required and should be filed in the same manner as the original consent. In line with ICH GCP R3 (Section 2.8.2), consent is an ongoing process throughout the study, not a one-off event at the time of enrolment.

3.12. Review of PIS and ICFs

When the CI has a completed draft of the PIS and ICF, this will be sent to the R&I Co-ordinator for review. The R&I Co-ordinator must ensure the PIS and ICF accurately reflects the study protocol, REC submission documentation and meet the minimum requirements detailed in this SOP. The PIS and ICF guidance document (GUI 51.002A) can also be used as a tool to help review the PIS and ISF and prompt for any missing content. The R&I Co-ordinator must also confirm that the PIS and ICF been reviewed by all relevant Sponsor representatives, including a Sponsor Pharmacist for any study involving a medicine, before the submission to the REC.

3.13. R&I Approval of PIS and ICFs

The final version of the PIS and ICF must be approved by Sponsor(s) before submission to the REC or any trial activity commences as per SOP 51.014. When all comments have been addressed and any issues have been resolved, the R&I Co-ordinator will confirm to CI, on behalf of relevant Sponsor stakeholders that the documents comply with Sponsor standards. The final documents will be named version 1.0 (V1.0) and dated as the day of Sponsor approval. Sponsor approval for REC/Regulatory submission is dependent upon review and approval of all other required documents (as per SOP 51.014). The SRA will save V1.0 of the PIS and ICF and any relevant correspondence in the TMF and e-folder (as per SOP 51.016).

4. Referenced documents

- GUI 51.002A - 'Participant Information Sheet and Informed Consent Form Guidelines'
- SOP 50.017 - 'Research & Innovation Document Management'
- SOP 51.001 - 'Protocol Development for Research Sponsored by NHSGGC or Co-Sponsored by NHSGGC and the University of Glasgow'
- SOP 51.014 - 'Preparation and Submission of IRAS Forms'
- SOP 51.016 - 'Preparation and Maintenance of a Trial Master File'
- SOP 51.021 - 'Review and Approval of Amendments for Research Sponsored by NHSGGC or Co-Sponsored by NHSGGC and the University of Glasgow'
- HRA Consent and Participant Information Guidance: Home - Consent and Participant information sheet preparation guidance.
- Adults with Incapacity (Scotland) Act 2000: Adults with Incapacity (Scotland) Act 2000 (legislation.gov.uk)
- Mental Capacity Act 2005: Mental Capacity Act 2005 (legislation.gov.uk)
- The Medicines for Human Use (Clinical Trials) Regulations 2004: The Medicines for Human Use (Clinical Trials) Regulations 2004
- HRA research Involving Children: Research involving children - Health Research Authority (hra.nhs.uk)
- HRA Principles of consent: Children and Young People (Scotland): Principles of consent: Children and Young People (Scotland) - Consent and Participant information sheet preparation guidance. (hra-decisiontools.org.uk)
- ICH GCP E6(R3) - Guideline For Good Clinical Practice

5. Related documents

- The GDPR and genomic data: GDSPolicy_Mitchell_Nov2020.pdf

6. Document History

Version	Date	Description
1.0	06/09/2012	Release of Version 1.0
2.0	14/07/2016	Updated to template v1.4. New author
3.0	24/05/2018	Minor clarifications
4.0	17/12/2018	Staff category updated
5.0	11/02/2022	Staff author changed; updated to R&I from R&D and to include innovation
6.0	30/06/2025	Added in more detail, removed sections around different patient populations (e.g. ALC and paediatrics) and types of research that involve different versions of the PIS/ICF. Removed procedure for hosted studies. Nomenclature changed in line with upcoming clinical trials regulations. Added associated GUI 51.002A.