Standard Operating Procedure			**51.002**
Participant Information Sheet and Consent Forms: Design and Approval			
Version	5.0		
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1. SOP Category
NHS GG&C Sponsor R&I

2. Staff Category
Research and Innovation (R&I)
Chief Investigators

3. Scope
This SOP applies to R&I Coordinators during the development (as required) and review of study specific participant information.

4. Purpose
This SOP describes the procedures which the R&I Office use when managing the design, review and approval of Participant Information Sheets (PIS) and Informed Consent Forms for research and innovation studies involving human subjects. These procedures are primarily for studies that Greater Glasgow & Clyde Health Board (GG&C) sponsor (or co-sponsor). Studies that GG&C hosts require scrutiny for approval purposes only.

4.1 Background
Informed consent is an agreement by an eligible person to participate in a research study after having been made aware of, and been afforded an adequate explanation of the risks and benefits of participation. 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. It is also essential that participants understand that they may withdraw from study participation, at any time, without giving a reason and without their usual care being affected. These principles should be applied equally to patients and healthy volunteers participating in research studies. Informed consent helps to ensure that agreement to participate in research studies is given freely and that no coercion or deception has been employed.

Consent must never be considered to be implied and can be given verbally and in written form. Verbal consent should only be taken in exceptional circumstances, in specified circumstances agreed by the relevant Research Ethics Committee (REC). If there is a witness(es) involved, the witness(es) must sign the informed consent form as a witness(es). There may be studies where the design and patient group are not conducive to all of the aforementioned rules being adhered to e.g. critical care and incapacitated adults. The arrangements for consent must be described clearly in the REC submission.

Wherever possible a written record of consent should be obtained. Participants should be supplied with a copy of their PIS and signed informed consent form for information purposes, a copy should be filed in the patient's medical notes and a subsequent copy should be retained

in the research study site file. Healthy volunteer studies only require a copy to be given to the subject and a copy held in the study file.

4.2 Responsibilities for PIS & Consent form design and approval

PIS and Informed Consent Forms should be agreed by Sponsors representatives (R&I Co-ordinators) and form part of the essential documentation submitted to a REC and R&I department for approval. Review of the content and suitability of a PIS and consent form is the remit of the REC.

Help with the design of the PIS and Informed Consent Form is one of the support services offered by the R&I department and is also one of the Board's Sponsor responsibilities. Once developed in conjunction with the Chief Investigator (CI), the R&I Co-ordinator is responsible for checking that the PIS accurately reflects the study protocol before this is submitted to the REC.

For hosted studies, errors or inconsistencies in the PIS identified during the approval process should be brought to the attention of the Sponsor for amendment at the earliest opportunity.

5. Procedures

If required, the R&I Coordinator can support the CI by directing them to websites providing guidance on designing PIS and informed consent forms (e.g. Health Research Authority (HRA) guidance on Participant Information Sheets and informed consent forms), providing examples of both documents, and advising on the minimum content of each document for studies sponsored by GG&C.

5.1 Design of a PIS

PIS are formalised and approved documents that are intended to provide trial subjects 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.
    - 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.
- Version control.
    - Each version of the PIS must be version controlled to ensure identification of it as a different version to that used previously.
- Amendment to a previously approved version must be approved by ethics prior to use unless withholding such an amendment until approval has been gained will harm the participant.
- Any amendment which might alter the risk:benefit ratio or add/remove/alter procedures for the participant and potentially affect their agreement to continuing participation will necessitate re-consenting the participant.

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. The HRA guidance on these specified topics is aligned to ICH GCP (E6 Guidelines) Section 4.8 – 4.8.19.

5.2 Design of an Informed Consent Form

When designing an informed consent form 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.
    - A legal representative may give consent on a subject's behalf
    - Consent given by another person should be based on what the legally acceptable representative thinks the subject would have decided if they were able to do so for themselves and is NOT what the legally acceptable representative thinks should be done in the subject's 'best interests'
- Consideration must be given to the current versions of the Mental Capacity Act (England, Northern Ireland and Wales) and the Adults with Incapacity (Scotland) Act regarding subjects who are permanently or temporarily mentally incapacitated.
- If the subject 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.
- Version control and approval for amendments is the same as for the PIS (above).
- Participants should specifically consent to their samples being subject to DNA analysis and their samples being used in conjunction with animal products.

The HRA website provides guidance on the specific headings and statements that must be included i.e. the title of Informed Consent, the version number of the PIS and the informed consent form, the research study title and protocol ID, the various statements that must be initialed by the subject, the identification of the investigator and study site and the signature section. The HRA guidance on participant information sheets and consent forms is aligned to ICH GCP (E6 Guidelines) Section 4.8 – 4.8.19. HRA guidance relating to informed consent should be consulted if required.

5.3 R&I Approval of PIS and Consent Forms

Approval means permission to undertake the study within NHS GG&C. For overall governance, PIS and Consent forms form part of the document set required by R&I for Management (Board level) approval. The versions of the PIS and Consent form(s) should be cross references against those submitted to the Research Ethics Committee (REC). However the review of the content of PIS and Consent forms falls under the remit of the REC.

For hosted studies, errors or inconsistencies in the PIS identified during the approval process should be brought to the attention of the Sponsor for amendment at the earliest opportunity. This should not prevent Management (Board level) approval from being given.

6. Referenced documents

None

7. Related documents

None

8. 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