STANDARD OPERATING PROCEDURE FOR WRITING A PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM

SOP NUMBER:	**Fife R&D SOP09**
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1. PURPOSE

This document describes the procedure to be followed by researchers when producing Participant Information Sheets (PIS) and Informed Consent Forms (ICF).

It is the responsibility of all staff using this SOP to ensure they are using the latest version of it. The latest version is available via StaffLink, the R&D tab of the Research, Innovation and Knowledge section of the NHS Fife website (www.nhsfife.org/research) and EDGE (https://www.edge.nhs.uk). For guidance, contact the R&D Department via fife.randd@nhs.scot

2. APPLICABILITY

This SOP applies to all staff involved in producing and reviewing a Participant Information Sheet and/or Informed Consent Form for any studies sponsored or co-sponsored by NHS Fife.

3. POLICY

3.1 Individuals participating in a clinical research study must give their voluntary, informed consent to take part. Informed consent is defined as “The process by which a participant voluntarily confirms his or her willingness to participate in a particular study, after having been informed of all aspects of the study that are relevant to the participant’s decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.”

3.2 The information provided to the potential participant is usually in the form of a Participant Information Sheet (PIS) (also sometimes referred to as Patient Information leaflet or brochure) which describes the study in layperson’s terms and helps inform their decision about whether to take part in a study. The PIS needs to be designed with the participant group in mind and contain sufficient information for the participant to fully understand the benefits and risks of taking part. The information should be presented clearly and in an unbiased fashion and the language style must be suitable for the participant population to understand and visual aids included where appropriate. The PIS should be suitable for the participant to take away and discuss with family and friends and to form the basis for discussions with the research team prior to informed consent.

3.3 The responsibilities of the participants should be clearly stated so the participants understand what is expected of them and what will happen to them, their data and samples during and after the end of the study. The responsibilities of the host organisation should also be clearly explained. The process for participants to contact the study team or to make a complaint must be detailed.

3.4 This information sheet and any other written, oral or electronic information given to the participant must be approved by the study Sponsor, a Research Ethics Committee prior to being used in a study and the appropriate NHS Board(s) or Trust(s), where the NHS is the host organisation.

3.5 It is important to remember that informed consent is not merely getting someone to sign a form; it is a process of information exchange, discussion and clarification of the information and taking the participant's verbal and written consent. This process begins when the initial contact is made with the potential participant in the study and continues throughout the time the person participates. The consent form is used as part of this process and provides tangible confirmation of the participant's agreement to take part and records that informed consent has been taken, when and by whom.

3.6 All documents must be version controlled with the version number and date on all pages and the document must be paginated using the 'Page X of Y' format (SOP04 - Version Control of Essential Documents).

3.7 The short study title and the IRAS (Integrated Research Application System) number must be added to either the header or the footer. The short title used must be consistent with other documentation.

3.8 The first page of the PIS and ICF should be on the headed notepaper of the institution(s) where the research is being carried out. If the PIS is for use in a multi-site study, a template PIS for all sites can be prepared leaving space for site information to be completed on approval.

4. PROCEDURE

4.1 Designing the Participant Information Sheet

4.1.1 Investigators should create documents following the guidance available on the HRA (Health Research Authority) website:
Informing participants and seeking consent - Health Research Authority (hra.nhs.uk).

4.1.2 In the section entitled 'Will it cost me anything to take part ', the text regarding remuneration must include:
e.g., 'up to £10 per participant per visit'

and must state whether a receipt is required to be able to give the refund.

4.1.3 The confidentiality section must include some wording to inform that:

'***Data may be accessed by authorised individuals from the Sponsor, regulatory authorities or host NHS organisation (e.g., NHS Fife) for monitoring and audit purposes'.***

This section must also make clear if identifiable data will be stored on computers outside of the NHS.

4.1.4 In a section entitled '***What if I am harmed by the study?*** *the suggested text is:*

It is very unlikely that you would be harmed by taking part in this type of research study. However, if you wish to complain or have any concerns about the way you have been approached or treated in connection with the study, you should ask to speak to [insert study team /phone] who will do their best to answer your questions. If you remain unhappy and wish to address your concerns or complaints on a formal basis, you should contact Patient relations Department at:

1st Floor, Hayfield House
Hayfield Road
Kirkcaldy
Fife
KY25AH
Phone: 01592 648153
Email: fife.patientrelations@nhs.scot

If something does go wrong, and you are harmed during the research, and this is due to someone's negligence then you may have grounds for a legal action for compensation against NHS Fife but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

4.1.5 A section must be included on the potential benefits or disadvantages of participating.

4.1.6 ALL study procedures must be listed.

4.1.7 A separate PIS and consent form is recommended for sub studies.

4.1.8 If it is intended to keep samples for future use, this must be mentioned in the PIS.

4.2 Designing the Informed Consent Form

4.2.1 The consent form must allow the participant to record their agreement and consent to all the different aspects of the study. This is particularly important when some aspects of a study may be optional.

4.2.2 The signatories on the consent form should be those who are involved in the consent process, e.g., the participant, the researcher or the participant's legal representative / nearest relative, guardian or welfare attorney.

4.2.3 Consent forms for a participant's legal representative should address them directly and should be written appropriately. The consent form must be clear that they are being asked for consent on behalf of the research participant.

4.2.4 An independent witness is not routinely required except in cases where potential participants are not able to read or write, or who are visually impaired etc.

4.2.5 If it is intended to keep samples for future use, this must be mentioned in the consent form.

4.2.6 If you have two statements that are optional, they should have both a yes and a no box for the participant to initial one or the other.

4.2.7 If applicable a statement must be added saying:

'I understand that relevant sections of my medical notes and/or study data may be looked at by responsible individuals from the study team, the Sponsor, NHS Board or regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records'.

4.2.8 If applicable, a statement must be added saying*:*

'I understand that my personal details and study data will be stored on secure computers, in secure cabinets or in archiving rooms at the XXXXX'.

4.2.9 If applicable, a statement must be added saying:

'***I agree to my samples being stored for future research'.***

5. ASSOCIATED DOCUMENTS & REFERENCES

SOP04 - Version Control of Essential Documents

Informing participants and seeking consent - Health Research Authority (hra.nhs.uk).

6. ABBREVIATIONS

ICF Informed Consent Form
IRAS Integrated Research Application System
PIS Participant Information Sheet
R&D Research and Development
SOP Standard Operating Procedure

7. DOCUMENT HISTORY

Version Number:	Edited by (job title):	Effective Date:	Details of Revisions Made:
1	Linsey Burd R&D Research Nurse	10 Nov 2014	New
2	Julie Aitken R&D Quality and Performance Lead	18 July 2022	This SOP was withdrawn after version 1 and converted to R&D WI35. This SOP has now been re-instated and adapted from R&D WI35 (v1). All NHS Fife R&D PIS & ICF template documents have been withdrawn and replaced with a reference to the guidance on the HRA website.

8. APPROVAL

APPROVED BY	Date
Professor Frances Quirk, Assistant Director Research, Innovation & Knowledge, NHS Fife Signature: 	18 July 2022