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NHS Norfolk and Norwich University Hospitals NHS Foundation Trust

SOP 310 Development of Participant Information Sheet and Informed Consent Form

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By:	All staff
For:	All staff involved in the conduct of research
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This Standard Operating Procedure (SOP) is available on the Research & Development pages on the NNUH website

Copies printed from the website are only valid on the day of printing.

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2. Definitions of Terms Used / Glossary

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
HRA	Health Research Authority
ICF	Informed Consent Form
ICH GCP	International Conference on the Harmonisation of Good Clinical Practice
MHRA	Medicines and Healthcare Products Regulatory Agency
NNUH	Norfolk and Norwich University Hospitals
PIS	Participant Information Sheet
PI	Principal Investigator
REC	Research Ethical Committee
R&D	Research and Development
RIN	Research and Innovation
SOP	Standard Operating Procedure
SI	Statutory Instrument
TMF	Trial Master File
UEA	University of East Anglia

3. Objectives

A Participant Information Sheet (PIS) and an Informed Consent Form (ICF) are essential to the process of obtaining informed consent from trial participants.

The objective of the PIS is to set out in writing what taking part in a study will involve for the participant including a summary of the study and rationale, how participation may impact on their treatment and/or their lives and the lives of others close to them. The ICF is a document by which the participant's understanding and agreement to participate in a study is captured.

4. Scope

This SOP gives general style guidance for designing a PIS and an ICF, however as not all research studies are the same, and different populations will have different information needs, different levels of understanding of medical terminology and different reading abilities, additional reading may be required. It is important that the level of detail is appropriate to the nature and burden of the study and risk/benefit profiles as well as the complexity of the protocol.

5. Purpose

The purpose of this SOP is to outline the process for designing a Participant Information Sheet (PIS) and Informed Consent Form (ICF) for a study.

6. Rules

The person writing the PIS and ICF MUST follow the recommendations of the World Medical Association's Declaration of Helsinki (WMA, 2013) and consult the following sources for up-to-date information on the required content and format:

- HRA toolkit www.hra-decisiontools.org.uk/consent/
- HRA Participant Information Quality Standards https://www.hra.nhs.uk/planning-and-improving-research/research-planning/participant-information-quality-standards/
- ICH GCP guidelines, particularly Topic E6 (R2) Good Clinical Practice
- The Office for Public Sector Information (OPSI) for guidance on the Medicines for Human Use (Clinical Trials) Statutory Instruments, 2004 and 2006.
- Applying a proportionate approach to the process of seeking consent HRA Guidance Date of Release: 17.01.2017 Version No. & Status: v1.01 17.01.2017 FINAL / Policy and Public Affairs Directorate
- If the study is being conducted in a country outside the UK, national regulations should be checked.

Care MUST be taken when preparing a PIS and ICF for vulnerable groups, these include:

- Minors (under 16)
- Incapacitated adults, defined as "adult[s] unable by virtue of physical or mental incapacity to give informed consent". It should be noted that the regulations in Scotland differ from those in England, Wales, and Northern Ireland
- People with learning difficulties
- Emergency situations

7. Procedure

7.1 Writing a Participant Information Sheet

The major considerations and required content of a PIS are outlined below:

- The Chief Investigator (CI) must ensure the PIS is submitted with the protocol and IRAS form for approval by a Research Ethics Committee (REC) and the Health Research Authority (HRA). Therefore, it is advisable to write the PIS after protocol development and prior to submission to the REC and HRA.
- The CI must ensure that a PIS is produced for a study

- The level of detail must be appropriate to the nature of the study and the population to be studied.
- The PIS MUST be written using simple, non-technical terms that a lay person will understand easily.
- Consider different ways of describing to potential participants what to expect: use of flow diagrams or pictures if you feel they bring more clarity to the information you are providing.
- To facilitate fair decision-making, you MUST state clearly what the risks and benefits of your study realistically are.

- Use a format best suited to the nature of the information that you wish to give potential participants, and which supports understanding: for example, use type as large as possible - size 16 font if you intend to recruit older people.

PIS content and structure

- Title
- Invitation and summary
- More details of what is involved
- Supporting information

- Consider the potential participants' perspective. There are issues that might be important to some people, such as: how many times they will have to visit the hospital, can they be accompanied and will they need time off work.

- Since the introduction of General Data Protection Regulation (GDPR) in 2018, the HRA have put together some guidance and suggested wording to help explain to potential participants how their information will be used. Ensure this is covered in the supporting information for transparency.

- Shorter information sheets are likely to be acceptable for studies with little or no intervention.

- If you intend to recruit two or more different groups of people, you MUST consider if you need to provide each group with their own PIS. For example, each group may have different levels of understanding, and/or different expectations of the perceived benefits of participating.

- All PIS must be version controlled and dated.

- Test your PIS with an appropriate group of people (patient groups or other members of the public) to get help.
- RECs will look more favourably upon applications if a Patient Participation Group has been involved in the design of or has reviewed the PIS

- A reference copy of the PIS must be retained in the Trial Master File (TMF).
- For each Investigator Site File the PIS must be printed on site headed paper.
  See **SOP 305 Creating and Maintaining a Trial Master File**

- If changes are made to the PIS, the version and date MUST be updated, reviewed by the sponsor, and submitted for approval to the REC and HRA.

- All previous versions of the PIS must be retained in the TMF.
- The front page must be struck through with a pen and “superseded” written clearly across it, signed, and dated.
- It is the responsibility of the PI and the Trial Manager at each site to ensure that all research staff associated with the trial are using the current REC/HRA approved versions of the PIS and have received appropriate consent training, and that training is documented as per **SOP 505: Training Requirements, Creating and Maintaining Training Records**

7.2 Writing an Informed Consent Form

The minimum requirements for writing the Informed Consent Form are highlighted below, further information is available on the HRA website, along with examples of ICFs (https://www.hra-decisiontools.org.uk/consent/examples.html).

- The CI must ensure that the ICF is submitted with the protocol and IRAS form for approval by a REC and the HRA. Therefore, it is advisable to write the ICF after protocol development and prior to submission to the REC and HRA.
- The CI must ensure that an ICF is produced for a study

	ICF Content and Structure • Itemise specific elements in bullet point format to clearly capture key points for potential participants to consent to • Include an area for participants to initial after each key point • Ensure adequate space for required signatories, and date of signature
	• All ICFs must be version controlled and dated.
	• A reference copy of the ICF must be retained in the Trial Master File (TMF). • For each Investigator Site File the ICF retained must be printed on the site letterhead. **See SOP 305 Creating and Maintaining a Trial Master File**
	• If changes are made to the ICF, the version and date MUST be updated, reviewed by the sponsor, and submitted for approval by the REC and HRA.
	• All previous versions of the ICF must be retained in the TMF. • The front page should be struck through with a pen and “superseded” written clearly across it, signed, and dated. • It is the responsibility of the PI and the Trial Manager at each site to ensure that all research staff associated with the trial are using the current REC/HRA approved versions of the ICF and have received appropriate consent training, and that training is documented as per **SOP 505 Training Requirements, Creating and Maintaining Training Records**

8. References and Related Documents

References
ICH GCP E6/SI 2004/1031, as amended SI 2006/1928 Health Research Authority HRA guidance for PIS and ICF design
World Medical Association’s Declaration of Helsinki (WMA, 2013)
HRA toolkit: www.hra-decisiontools.org.uk/consent/
ICH GCP guidelines, Topic E6 (R2) Good Clinical Practice
The Office for Public Sector Information (OPSI) for guidance on the Medicines for Human Use (Clinical Trials) Statutory Instruments, 2004 and 2006.

SOP No.	**SOP Title**
SOP 315	Obtaining Written Informed Consent from Competent Adults in Clinical Trials
SOP 316	Distance (remote) Consenting for Children and Neonates in Research Studies
SOP 305	Creating and Maintaining a Trial Master File
SOP 505	Training Requirements, Creating and Maintaining Training Records

9. Approval

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10. Training Implication

Training Implication	**Yes**
Actions required	• Review