

SOP Number

007

SOP Title

Preparation of Participant Information Sheets and Informed Consent Forms

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1. PURPOSE

The purpose of this SOP is to provide instructions for the development and review of participant information sheets and consent forms.

2. INTRODUCTION

Participants in clinical research must be provided with information on which to base an informed decision on initial and continued participation. Information provided should be balanced, comprehensive and comprehensible. Potential participants should be given appropriate time to read and understand the content prior to consenting, including the opportunity to ask, and have answered, questions and concerns.

3. SCOPE

The scope of this procedure is for all clinical research studies sponsored by the University of Oxford, but may also be used for other clinical research studies at the discretion of the unit.

4. DEFINITIONS

Participant/Patient Information Sheet (PIS)

An approved document which provides detailed information on the study, and to which the participant can refer in order to make an informed decision about participation.

Where there are additional participant-facing documents (e.g. Invitation letter), these should be treated in the same manner as the PIS.

Informed Consent Form (ICF)

An approved form on which a participant's informed consent to take part in a study is recorded, and which will reference the current approved version of the PIS.

5. RESPONSIBILITIES

Chief Investigator

Compilation of the study PIS and ICF, and their submission to Research Ethics Committee (REC). This responsibility may be delegated to a member of the study team.

Sponsor

Review and approval of PIS and ICF with reference to the protocol and ethical guidelines.

6. SPECIFIC PROCEDURE

6.1 Generation of the Participant Information Sheet and Informed Consent Form

Once a final draft version of the protocol has been agreed, the PIS and ICF can be developed, along with all other documents for submission to the REC.

Both the PIS and ICF will be produced according to the guidance provided by the Health Research Authority (HRA) in the UK, or country-specific equivalent. Additional guidelines are available, and these are referenced in section 8. Information provided will include clear identification of the name of the study, name of Sponsor, name of the Chief Investigator, local site address, Study

Team contact details, version number and date as approved by the named REC. Where there are external funders or collaborators, these should be acknowledged within the PIS.

Information should be written in a style appropriate for the target population, avoiding coercive language, and in such a way that is easily understood by a lay person. All participant procedures covered within the protocol, together with relevant safety information, must be presented within the PIS.

In the event that a study intends to recruit participants with a range of understanding (e.g. children or young people, adults without capacity), alternative approved versions should be constructed. Additionally, older children who are capable of assent should be provided with a separate and approved version of the PIS and an approved assent form. If the target population includes participants with limited facility in English, validated translations of approved documents should be used.

Where samples are collected, consideration should be given to gifting of samples to the University of Oxford, or other Sponsor, as appropriate. If applicable, the consent form should include agreement that the participant foregoes commercial interest, may be transferred to locations outside of the UK, and/or be used in future studies.

Where identifiable data is to be transferred, consideration should be given to the information in the PIS detailing safeguards for the transfer. If identifiable data is to be sent out of the EU, the consent form should include agreement for this. It is good practice to inform participants in the PIS anonymous data sharing plans, but this data can be shared without explicit participant consent.

The PIS and ICF should be reviewed within the unit, prior to sending for Sponsor review.

6.2 Sponsor Review

Once the documents are believed to be in satisfactory condition and consistent with the protocol, they will be sent to the Sponsor for review. Timelines for comments and updates to the documents will be agreed.

Where the study is being run in multiple countries, Sponsor review will usually concentrate on the UK versions only of the PIS and ICFs. These will then be adapted to comply with country specific regulatory requirements.

Sponsor review of the PIS and ICFs will be undertaken alongside review of all other documents to be included within the REC submission.

6.3 Research Ethics Committee Review

If, on review of the PIS and ICF, changes are requested by the REC, copies of the updated documents will be provided to the Sponsor.

REC approval of the PIS and ICF has to be granted before they are put into use in the consent process.

6.4 Ongoing Review and Amendments

During the course of the study, it may be necessary to re-write and re-issue either the PIS or ICF, or both. All documents should be reviewed on an ongoing basis to ensure continued relevance. As a minimum, this is to be carried out when new information related to the study becomes available and it is necessary to include this information in the PIS and/or ICF.

Any amended documents are to be sent to the Sponsor for review and then on to the HRA, REC and Competent Authority as required.

7. RELATED DOCUMENTS

University of Oxford Core SOP 002 - Protocol Development

8. REFERENCES

ICH Harmonised Tripartite Guideline for Good Clinical Practice (ICH GCP), 1996
 World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects, 2010
 Information Sheets & Consent Forms. Guidance for Researchers and Reviewers. HRA, 2016
<http://www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/consent-and-participant-information/>
 MHRA Good Clinical Practice Guide, 2012
 FDA guide to informed consent -
<http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm>

9. CHANGE HISTORY

Version No.	Effective Date	Significant Changes	Previous Version No.
2.0	See page 1	Changes to remove references to NRES, add reference to the HRA and update websites links. Also to add consideration around data transfer and Sponsor review of PIS and ICFs on multinational studies.	1.0