

University of Hertfordshire

PARTICIPANT INFORMATION

Clinical Trials Support Network (CTSN)

Standard Operating Procedure for the
Provision of Participant Information for University of Hertfordshire Sponsored or
co-sponsored Clinical Research Studies

SOP Number: gSOP-20-01	Effective Date: 26 th April 2018
Version Number: v1.4	Review Date: 3 years (or as required)

1.0 BACKGROUND

This is a University of Hertfordshire standard operating procedure. University of Hertfordshire (UH) acknowledges West Hertfordshire Hospitals NHS Trust (WHHT) Research & Development (R&D) which has allowed UH to use the SOPs developed by WHHT where possible, modified for local implementation.

This document sets out the procedures to be followed by all staff who produce information about research studies to be provided to potential participants prior to the participant consenting to participate in the study. Where there are potential conflicts between different collaborating organisations' SOPs, project level working instructions should be developed, to determine precedence.

It provides guidance on how to produce, implement and disseminate Participant Information to staff for the purpose of providing information to a potential study participant to ensure compliance with the relevant regulations.

2.0 PURPOSE

- To ensure all UH sponsored/co-sponsored studies have appropriately designed participant information documents such as participant information sheets and consent forms to assist staff in consenting Participants.
- To ensure that the participant information documents including trial advertisement meet all ethical and legal requirements.

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3.0 APPLICABLE TO

This applies to all staff involved in clinical research sponsored/co-sponsored by UH, including: Chief Investigators, Principal Investigators, Research Fellows, Consultants, Statisticians, Clinical Trial Pharmacists, Research Managers, Research Nurses, Clinical Trial Practitioners, Allied Health Professionals, Trial Managers, Clinical Studies Officers, Data Managers, Research Assistants and students.

4.0 RESPONSIBILITIES

The Chief Investigator (CI) or delegated individual (DI) must ensure that all participants are fully informed about the trial before they provide consent, therefore, they should ensure that the participant information documents contain all the relevant information regarding the trial and are comprehensible to potential trial participants.

The research personnel delegated the responsibility of informed consent on the study delegation log must ensure that the participant information sheets are used to assist in the consenting procedure.

The Trial Managers or other appropriate delegated personnel are responsible for ensuring that the correct versions of the Participant information documents are available and that they have all necessary approvals before being put into practice.

The Health Research Authority (HRA) and Sponsor are responsible for ensuring that the Participant information provided is sufficient for the trial and that they will ensure that the participant is fully informed before they are consented. They are also responsible for considering if trial participants require re-consenting as a result of any amendments to the participant information.

For studies conducted in NHS patients the Trust R&D departments are responsible for ensuring that the participant information documents have the necessary regulatory approvals in place before implementation of these documents is granted.

5.0 PROCEDURE

Participant information documents should inform the participant about the nature and conduct of the trial, examples of Participant information documents include informed consent forms, participant information sheets, questionnaires, GP letters, advertisements etc.

The participant information documents should only be developed once the protocol has been finalised and agreed by appropriate team members and associated departments such as R&D, statistics, pharmacy, imaging etc (see gSOP-14).

All of the participant information documents must be clearly version and date controlled to ensure that the correct versions are used when amendments occur as detailed in section 5.2

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A separate participant information sheet and informed consent form must be provided in cases where there is more than one element to the study, for example, interview phase, tissue biomarker or PET scan sub study. For healthy volunteer studies a separate participant information sheet and consent form may be required for registration onto the TOPS database. Please see gSOP-038 Management of healthy volunteers in research studies.

When designing any documents for a study that will be used by the participant it is important to ensure that they are:

- clear
- concise
- non-technical, but provide appropriate amount of detail
- sensitive
- invitational rather than persuasive
- version and date controlled

5.1 Development of Participant Information

5.1.1 Participant Information Sheet

The participant information sheets are a detailed guide to the study written in lay terms with information regarding participating in the trial. They are a vital part of the informed consent procedure as they are used to help the participant determine if the study interests them and if they would like to receive further information from a doctor regarding participating.

Detail regarding the content and examples of wording can be found on the National Research Ethics Service (NRES)/ Health Research Authority (HRA) website under – *Consent and Participant Information Sheet Preparation Guidance*.

It is important to ensure that if any participant details or information is to be transferred outside of the country that a statement such as the following should be included,

‘Some non-EEA countries, including the U.S. may not offer the same levels of privacy protection that you have in the UK.’

5.1.2 Consent Form

The consent form documents that informed consent has been taken, after having been informed of all aspects of the trial 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.

Please refer to gSOP-04 for further information on Obtaining and Documenting Informed Consent in Research.

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For details about the content and examples of wording in consent form, please refer to the HRA website.

5.1.3 GP Letters

The GP letter should inform the doctor of their patient's participation in the trial and provide contact details of the team responsible for the participant whilst they are participating in the trial. It may be helpful to attach the participant information sheet (PIS) or summary for the GP's information.

5.1.4 Questionnaires

It is important where possible to use questionnaires that have been validated as appropriate tools to collect the required information, for example, the quality of life tool Euroqol (EQ-5D).

These questionnaires should be discussed fully with the study statistician as they will be a vital tool in collecting the required data for the study.

It is important to consider how these documents will be completed, i.e. in conjunction with either a doctor or nurse or if they will be sent in the post to be completed. The method for completion of the questionnaires should be documented in the protocol.

5.1.5 Advertisement

If a trial uses any advertisement for participant recruitment, they should contain a brief description of the purpose of the trial and the type of participant that would be recruited.

When designing the advertisements recruitment measures taken should be appropriate and not coercive i.e. advertisements are invitational rather than persuasive. All study advertisements should be reviewed by the HRA/REC.

They should also contain appropriate contact details for further information.

5.1.6 Expenses and payments

Explain if expenses (e.g. travel, meals, child-care, compensation for loss of earnings, etc.) are available and consider whether any vouchers, gifts, etc. which you are intending to give as a 'thank-you' for participation, should be detailed in the information sheet. The arrangements for any other payment, e.g. for Phase I volunteers, should be given including, if necessary, an explanation of how payments may be influenced by the duration of involvement in a study or factors such as the completeness of diaries.

5.1.7 Complaints

A contact number should be given. This may be the researcher, who can try to solve the problem in the first instance. However, a participant may not wish to complain to the researcher if he/she is the object of the complaint and may wish to make a more formal complaint. Details of the UH Secretary/Registrar

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should be included. The following text could be used:

“If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions [contact number]. If you remain unhappy and wish to complain formally, you can do this [insert details e.g. Complaints Procedure]. Details can be obtained from [insert details]

Appropriate redress and/or compensation should be available and details of insurance/indemnity schemes should be given. Every care will be taken in the course of this clinical trial. However in the unlikely event that you are injured by taking part, compensation may be available.”

5.2 Participant Information Ongoing Review, Amendments and Re-consenting Requirements

5.2.1 The study information should be continually reviewed by the CI or the delegated individual (DI) and the relevant oversight committees (Please see gSOP-11) to ensure that Participant safety and the risk/benefit ratio is maintained.

5.2.2 Any Participant information document amendments should be produced in conjunction with the appropriate research team members, study statistician and be reviewed by Sponsor/CTSN before being submitted as an amendment (please see gSOP-09).

5.2.3 It is important when amending these documents to consider whether re-consenting participants is required as a result of changes in procedures or updates to safety information, however, this should also be reviewed by both the HRA and the sponsor.

5.2.4 All document versions should be kept in the TMF although it is important to ensure that superseded versions are clearly marked (gSOP-06).

5.2.5 It is important that a version control log is maintained detailing a summary of the amendment and when that version received the necessary approvals.

6.0 RELATED DOCUMENTS

- National Research Ethics Service (NRES)/ HRA website under – Consent and Participant Information Sheet Preparation Guidance
- gSOP-04 Informed Consent
- gSOP-06 TMF
- gSOP-09 Amendments
- gSOP-11 Sponsor Oversight
- gSOP-14 Writing Research Protocols
- RE01- Studies Involving Human Participants

7.0 APPENDICES

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- Appendix 1- Definitions

8.0 VERSION HISTORY

Revision Chronology:		
Version Number	Effective Date	Reason for Change

9.0 AUTHORSHIP & APPROVAL

Author

Signature _____ Date _____

Pro-Vice Chancellor (Research & Enterprise) Approval

Signature _____ Date _____

10. AGREEMENT

Please detach and retain within your training files

I have read and understood the contents and requirements of this SOP (ref gSOP-20-01) and accept to follow University policies implementing it.

<p>Recipient</p> <p>Signature:Date:</p> <p>Name & Position:</p>
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Please retain copy of the signed form for your reference in your training file

Appendix 1: Definitions

Chief Investigator (CI) - A Registered Physician, Dentist, Pharmacist or Registered Nurse who has overall responsibility for the conduct of the trial.

Clinical Trial - A research study in which one or more human participants are prospectively assigned to one or more interventions (which may include placebo or control) to evaluate the effects of those interventions on health outcomes.

Investigational Medicinal Products (IMP) - means a pharmaceutical form of an active substance or placebo being tested, or used as a reference in a clinical trial. This includes a medicinal product which has a marketing authorisation but is, for the purposes of the trial -

(a) used or assembled (formulated or packaged) in a way different from the form of the product authorised under the authorisation,

(b) used for an indication not included in the summary of product characteristics under the authorisation for that product, or

(c) used to gain further information about the form of that product as authorised under the authorisation

Principal Investigator (PI) - A Registered Physician, Dentist, Pharmacist or Registered Nurse who has responsibility for the conduct of the trial at a host site.

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