PATIENT INFORMATION

Research & Development

Standard Operating Procedure for the Provision of Patient Information for West Hertfordshire Hospitals NHS Trust Sponsored CTIMPs

SOP Number : SOP-20-06	**Effective Date:** October 2021
Version Number: v06	**Review Date:** 2 - 3 years

1.0 BACKGROUND

This document sets out the procedures to be followed by all West Hertfordshire Hospitals Trust (WHHT) staff who produce information about research studies to be provided to potential participants prior to the participant consenting to participate in the study.

It provides guidance on how to produce, implement and disseminate patient information to staff for the purpose of providing information to a potential study participant to ensure compliance with the Trust's policies.

2.0 PURPOSE

- To ensure all WHHT sponsored studies have appropriately designed patient information documents such as Patient Information Sheets (PIS) and consent forms to assist staff in consenting patients

- To ensure that the patient information documents including trial advertisement meet all ethical and legal requirements

3.0 APPLICABLE TO

All relevant Trust employees involved with Clinical Trials of an Investigational Medicinal Product (CTIMP) research sponsored by WHHT including, but not limited to, Unit Heads, Chief Investigators (CI), Principal Investigators (PI), Consultants, Co-investigators, Research Fellows, Clinical Trial Pharmacists, Research Managers, Statisticians, Research Nurses, Allied Health Professionals, Trial Coordinators, the Research & Development Steering Group (RDSG) & Data Managers.

4.0 RESPONSIBILITIES

The CI or delegated individual (DI) must ensure that all patients are fully informed about the trial before they provide consent, therefore, they should ensure that the patient 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 PISs are used to assist in the consenting procedure. (see SOP-04)

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

The Health Research Authority (HRA) and RDSG are responsible for ensuring that the patient information provided is sufficient for the trial and that they will ensure that the patient 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 patient information. (see SOP-09)

All study documents will require HRA approval before they can be used. The R&D Department is responsible for ensuring that the patient information documents have the necessary regulatory approvals in place before implementation of these documents is granted.

5.0 PROCEDURE

Patient information documents should inform the patient about the nature and conduct of the trial, examples of patient information documents include informed consent forms, PIS, questionnaires, GP letters, advertisements etc.

The patient 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 SOP-08 and SOP-14)

All of the patient 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

A separate patient information sheet and informed consent form must be provided in cases where there is more than one element to the study, for example, tissue biomarker or PET scan sub study.

When designing any documents for a study that will be used by the patient 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 Patient Information

5.1.1 **Patient Information Sheet**

The patient 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 patient 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 Medical Research Council (MRC UKIR)/ HRA website under – Consent and Participant Information Guidance.

It is important to ensure that if any patient 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 subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form (see SOP-04).

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 letters should inform the doctor of their patient's participation in the trial and provide contact details of the team responsible for the patient whilst they are participating in the trial. It may be helpful to attach the 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 EORTC QLQ-C30.

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 patient 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.

They should also contain appropriate contact details for further information.

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

5.2.1 The study should be continually reviewed by the CI/DI and the relevant oversight committees (see SOP-11) to ensure that patient safety and the risk/benefit ratio is maintained.

5.2.2 Any patient information document amendments should be produced in conjunction with the appropriate research team members, study statistician and be reviewed by RDSG/the R&D Department before being submitted as an amendment (see SOP-09).

5.2.3 It is important when amending these documents to consider whether re-consenting patients 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 RDSG.

5.2.4 All document versions should be kept in the Trial Master File (TMF) although it is important to ensure that superseded versions are clearly marked (see SOP-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

- Medical Research Council (MRC UKIR)/ HRA website under – Consent and Participant Information Guidance
- SOP-04- Informed Consent
- SOP-06- Trial Master File
- SOP-08- Role of CI, Pharmacy, Nuclear Medicine and R&D
- SOP-09- Amendments
- SOP-11- Sponsor Oversight
- SOP-14- Writing Research Protocols

7.0 APPENDICES

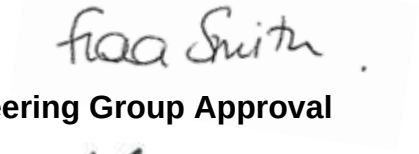
Appendix 1.0 - Definitions

8.0 VERSION HISTORY

Revision Chronology:		
Version Number	**Effective Date**	**Reason for Change**
SOP-20-06	**October 2021**	1. Change from general Standard Operating Procedures (gSOP) to SOP 2. Removal of the '10.0 Agreement' from the template - all agreement signatures will be collated on a new 'SOP Signature Sheet Document' 3. Other minor amendments and clarification of terms following review
gSOP-20-05	**October 2017**	Minor amendments following review
gSOP-20-04	**01/10/15**	Minor amendments following review
gSOP-20-03	**22/05/2014**	Minor amendments following review
gSOP-20-02		SOP modified for implementation at ENHT/WHHT (Then WHHT was part of consortium)
gSOP-20-01 (MVCC)		SOP modified for implementation at MVCC (Then WHHT was part of consortium)

9.0 AUTHORSHIP & APPROVAL

Author

Signature  **Date** 28/10/2021

R & D Steering Group Approval

Signature  **Date** 28/10/2021

Appendix 1: Definitions

Chief Investigator (CI)
The investigator with overall responsibility for the research. In a multi-site study, the CI has co-ordinating responsibility for research at all sites. All applications for ethical review should be submitted by the CI

Clinical Trial
A clinical study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study protocol. Participants may receive diagnostic, therapeutic, or other types of interventions. A Study Type.

Investigational Medicinal Products (IMP)
A pharmaceutical form of an active substance or placebo being tested, or to be tested, or used, or to be used, as a reference in a Clinical Trial, and 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)
The investigator responsible for the research site. There should be one PI for each research site. In the case of a single-site study, the chief investigator and the PI will normally be the same person.