Document Title: Patient Information Sheets and Consent Forms: Development and Implementation

Document Number: PTUC SOP020

Staff involved in development: *Job titles only*	Senior R&D Manager, R&D Administration Manager, Research Officers
Document author/owner:	R&D Administration Manager
Directorate:	Research and Development
Department:	Research and Development
For use by:	NHS Staff Trust-Wide
Review due:	October 2021

Summary of Significant Change(s) (for this version only)

Section(s):	Modification:
	Put into new template
4	Deleted 4.1.j as this was a repeat of 4.1.h

Key Points of this Document

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

1 Purpose and Contents

a. This document defines the Trust's procedures for developing and implementing patient information sheets and patient consent forms for the purpose of recruiting participants for studies sponsored by Royal Papworth Hospital and or managed by Papworth Trials Unit Collaboration (PTUC)

b. The document details the requirements for providing information to potential research participants as described in Good Clinical Practice (GCP: 'a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected').

c. The document provides guidance on the processes involved in producing and disseminating information to ensure participants are adequately informed about research studies prior to consenting to participate in research so as to comply with the Trust's policies on Consent.

2 Roles & Responsibilities

a. This Policy applies to all personnel that are conducting research at the Trust.

b. Staff developing information to be provided to potential research participants must comply with the requirements set out in section 4.

c. The Chief Investigator is responsible for the production of patient information documents and ensuring that these have been approved by the appropriate regulatory bodies prior to their use.

3 Policy

a. This SOP is mandatory and, as per the Trust's Information Governance and Records Management framework, non-compliance with may result in disciplinary procedures.

4 Procedure

4.1 Development of documents

a. Patient Information Sheets (PIS) and consent forms should be written using the latest guidance from the National Research Ethics Committee http://www.hra-decisiontools.org.uk/consent/content.html .

b. Templates adhering to these guidelines for Patient Information Sheets and Consent Forms (TPL015) are available to download from the R&D Intranet pages. Please note that some sections may not be relevant and can be deleted. In other cases, it may be necessary to include additional sections (e.g. where samples are being taken, a line should be included in the consent form indicating whether patients consent to the samples being obtained). These templates should be altered where appropriate (e.g. when taking retrospective consent, or consenting a relative of a patient who is unable to provide informed consent etc).

c. Local Hospital letterhead should be used for all information provided to patients (only necessary on first page of Patient Information Sheet and Consent Form).

d. All documents provided to patients should be clearly titled and have numbered pages, with a date and version number in the footer to ensure the most recent is used. For Papworth-sponsored studies, refer to SOP060 Version Control of Study Documents for guidance about the preferred version numbering system.

e. The relevant local contact names and numbers should be included on all information.

f. Patient information sheets and consent forms will be reviewed as part of the Research Governance process (see SOP034 Trust Confirmation of Capacity and Capability to Conduct Research Studies).

g. For the informed consent process see SOP003 Informed Consent for Research Studies.

h. Any amendments to the PIS and consent form must be dealt with according to SOP037 Amendments to Research Documents and SOP009 Project Management of Clinical Trials. Project Manager is to check version control.

i. For multi-centre Papworth sponsored studies the current approved versions of the PIS and consent form must also be disseminated to each participating site, as well as Papworth (as per SOP037 Amendments to Research Documents and SOP009 Project Management of Clinical Trials).

5 Risk Management / Liability / Monitoring & Audit

a. The R&D SOP Committee will ensure that this SOP and any future changes to this document are adequately disseminated.

b. The R&D Department will monitor adherence to this SOP via the routine audit and monitoring of individual clinical trials and the Trust's auditors will monitor this SOP as part of their audit of Research Governance. From time to time, the SOP may also be inspected by external regulatory agencies (e.g. Care Quality Commission, Medicines and Healthcare Regulatory Agency).

c. In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the Senior R&D Manager should be gained before any action is taken. SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.

d. The Research and Development Directorate is responsible for the ratification of this procedure.

Further Document Information

Approved by: *Management/Clinical Directorate Group*	Research and Development Directorate
Approval date: *(this version)*	[Current active version approved date]
Ratified by Board of Directors/ Committee of the Board of Directors:	STET
Date:	N/A
This document supports: *Standards and legislation*	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK policy framework for health and social care research
Key related documents:	Trust Research Policy

Equality Impact Assessment: Does this document impact on any of the following groups? If YES, state positive or negative, complete Equality Impact Assessment Form available in Disability Equality Scheme document DN192 and attach.

Groups	Disability	Race	Gender	Age	Sexual orientation	Religious & belief	Other
Yes/No	NO	NO	NO	NO	NO	NO	NO
Positive/Negative	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Review date:	October 2021

Version Control

Version	Date effective	Valid to	Approved by	Date of approval
1.0		July 2011		5 August 2009
2.0	28 December 2012	December 2015	RDD (Dr Ian Smith on behalf of RDD)	14 December 2012
3.0				
4.0				

I certify the contents of this SOP has been reviewed and ratified

..... 30th November 2018

Signed by Dr Ian Smith, Clinical Director of R&D — Date

SOP release date: 12th December 2018