Document Title: Participant 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 Operational Manager, Clinical Project Manager
Document author/owner:	Senior R&D Manager
Directorate:	Research and Development
Department:	Research and Development
For use by:	NHS Staff Trust-Wide
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Summary of Amendments

Section(s):	Modification:
5	Put into new template and reference to TPL052 Patient summary sheet
4	Deleted 4.1.j as this was a repeat of 4.1.h

Key related documents:	Trust Research Policy SOP060 Version Control of Study Documents SOP034 Trust Confirmation of Capacity and Capability and Sponsor Green Light Notification to Conduct Research Studies SOP003 Informed Consent for Research Studies SOP037 Amendments to Research Studies

	SOP009 Project Management of Research Studies TPL015 Participant Information Sheets and Informed Consent Form TPL052 Patient Summary Sheet

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 Participant Information to Royal 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 Participant Information Sheets and participant Informed Consent Forms for the purpose of recruiting participants for studies sponsored by Royal Papworth Hospital and or managed by Royal 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 participant 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 participant 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. Participant Information Sheets (PIS), Informed Consent Forms and patient summary sheet – Simple outline of the study (if using) 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 Participant Information Sheets and Informed Consent Forms (TPL015) and patient summary sheet (TPL052) are available to download from the R&D Intranet pages and IQM. 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 Informed Consent Form indicating whether participants 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 participant who is unable to provide informed consent, etc.).

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

d. All documents provided to participants 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 Royal 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. Participant information sheets, consent forms and patient summary sheet will be reviewed as part of the Research Governance process (see SOP034 Trust Confirmation of Capacity and Capability and Sponsor Green Light Notification to Conduct Research Studies).

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

h. Any amendments to the PIS, Informed Consent Form or patient summary sheet must be dealt with according to SOP037 Amendments to Research Studies and SOP009 Project Management of Research Studies. Project Manager is to check version control.

i. For multi-centre Royal Papworth sponsored studies the current approved versions of the PIS, Informed Consent Forms and patient summary sheet must also be disseminated to each participating site, as well as Papworth (as per SOP037 Amendments to Research Studies and SOP009 Project Management of Research Studies).

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 (2023)

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

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