Document Title: Participant Recruitment

Document Number: R&D SOP031

Staff involved in development: *Job titles only*	Senior R&D Manager, R&D Operational Manager, Clinical Project Managers
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Department:	Research and Development
For use by:	NHS Staff Trust-Wide
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Summary of Amendments

Version:	Modification:
	Minor amendments throughout

Key Points of this Document

- This document sets out the procedures to be followed by all Royal Papworth Staff who are involved in the recruitment of participants for clinical trials and research studies at, or sponsored by, Royal Papworth Hospital NHS Foundation Trust.

- It provides guidance on how recruitment is planned, performed and recorded so as to ensure compliance with the Trust's policies, Good Clinical Practice and the UK Policy Framework for Health and Social Care Research (2018).

1 Purpose and Content

a. This document defines the Trust's research procedures for identifying and recruiting participants into clinical trials being performed at, or sponsored by, Royal Papworth Hospital NHS Trust.

b. This document clarifies the requirements for documenting the identification, screening and enrolment of trial participants so as to conform with Good Clinical Practice.

c. The document describes the core procedures that are required in respect to designing, monitoring and performing participant recruitment into clinical trials. Exact procedures for identifying and approaching participants will be detailed in the study protocol (see PTUC SOP019: Research Protocol Design).

d. The subsequent receiving of informed consent to participate in a research study is outside the scope of this SOP and is described in R&D SOP003: Informed Consent for Research Studies.

2 Roles & Responsibilities

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

b. Staff involved in the conduct of clinical trials hosted at or sponsored by Royal Papworth Hospital must comply with the requirements set out in section 4.

c. The Principal Investigator (PI) for each study within the Trust is responsible for the conduct of the trial at the Trust. They should be aware of the recruitment strategy and how recruitment is progressing. Delegated team members will have the responsibility of conducting participant recruitment and maintenance of the screening log and the recruitment log.

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 Overview

a. There are several steps involved in participant recruitment. These can be summarised as:

1. identifying a potentially suitable participant;
2. screening the participant to ensure that they meet the inclusion and exclusion criteria;
3. receiving informed consent from the participant;
4. enrolment in the study.

b. Good Clinical Practice requires that records are kept of every participant that undergoes pre-trial screening i.e. details of all participants approached for a study should be maintained. For the purposes of this SOP, this shall be referred to as the screening log.

4.2 Recruitment Strategy

a. During study set-up and before the first participant is enrolled, a recruitment strategy should be planned and all research staff working on the clinical trial must be familiar with the process.

b. The clinical teams should be made aware by the research team of clinical trials within their areas to facilitate participant recruitment.

c. Recruitment goals should be set during study review and feasibility by estimation of likely participant numbers, and accounting for the length of the recruitment period. Recruitment targets should be realistic considering staff leave and appropriate set up period. Recruitment rates must be regularly assessed with the strategy being re-evaluated promptly if targets are not being met.

d. Staff involved in recruitment tasks must be clearly identified on the study's Delegation Log (see R&D SOP055: Roles and Responsibilities for the Conduct of Research Studies and Clinical Trials including CTIMPs (Clinical Trials of Investigational Medicinal Products)).

e. The delegated staff will keep a record of all participants who are screened for potential eligibility, and meet the inclusion criteria. This will be kept confidential but contain as a minimum: the participant's initials, date of birth, date screened, hospital number and if the participant was subsequently enrolled.

f. Participant's informed consent should be received according to R&D SOP003 Informed Consent for Research Studies. It is important that participants are aware if they are consenting for tests to be performed that will determine their eligibility for a particular clinical trial, and that dependant on the results, they may or may not be eligible to continue in the trial.

g. After enrolment, the participant's details will be added to a recruitment log. As a minimum this will record: the participant's full name, date of birth, hospital number, study code or ID number, and the date of randomisation where applicable.

h. The recruitment log must be archived at the end of the study as a record detailing all the participants enrolled in the clinical trial, with participant name, year of birth and treatment allocation (if randomised). Refer to PTUC SOP011 Archiving.

i. The recruitment log must be stored securely at all times as required by GCP and the Data Protection Act.

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 (2018)
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							

Review date:	October 2025

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

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Signed by Dr Patrick Calvert, Clinical Director of R&D — Date