Document Title: Participant Recruitment

Document Number: R&D SOP031

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Department:	Research and Development
For use by:	NHS Staff Trust-Wide
Review due:	June 2029

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Summary of Amendments

Version:	Modification:
V5.0	Minor amendments throughout
V6.0	Minor amendments to reflect changes in regards to the new clinical trial E6 R3 regs

Key related documents:	SOP003 Obtaining Informed Consent for Research Studies SOP011 Archiving of Research Studies SOP019 Research protocol Design SOP055: Roles and Responsibilities for the Conduct of Research Studies and Clinical Trials including CTIMPs

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 and Good Clinical Practice.

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 for participant recruitment into clinical trials. The 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: Obtaining 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 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:

- Identifying a potentially suitable participant.
- Screening the participant to ensure that they meet the inclusion and exclusion criteria.
- Receiving informed consent from the participant.
- 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 plan should be identified and all research staff working on the clinical trial must be familiar with the process.

b. Consultants and clinical teams should be made aware by the research team of clinical trials within their areas to facilitate participant recruitment. If applicable permission should be sought to approach patients under another consultant.

c. Recruitment target should be agreed during study feasibility and set-up by estimation of likely participant numbers, and accounting for the length of the recruitment period. Recruitment targets should be realistic. Recruitment rates must be regularly assessed with the target 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 SOP055: Roles and Responsibilities for the Conduct of Research Studies and Clinical Trials including CTIMPs. The Delegation Log must be signed off prior to commencing recruitment and kept updated when there are staffing changes on the trial.

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 Obtaining 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 of Research Studies.

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) (Amendment) Regulations 2025 (and any subsequent amendments) UK Policy Framework for Health and Social Care Research version 3.3 (07/11/17) and authorised amendments thereafter

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

Review date:	June 2029