Papworth Hospital NHS
NHS Foundation Trust

Document Title: Patient Recruitment

Document Number: R&D SOP031

Staff involved in development: *Job titles only*	Senior R&D Manager, R&D Administration Manager, Clinical Project Managers
Document author/owner:	R&D Administration Manager
Directorate:	Research and Development
Department:	Research and Development
For use by:	NHS Staff Trust-Wide
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Summary of Significant Change(s) (for this version only)

Section(s):	Modification:
	Minor administrative amendments

Key Points of this Document

- This document sets out the procedures to be followed by all Papworth Staff who are involved in the recruitment of patients or participants for clinical trials and research studies at, or sponsored by, 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 Research Governance Framework.

1 Purpose and Content

a. This document defines the Trust's research procedures for identifying and recruiting participants into clinical trials and research studies being performed at, or sponsored by, 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 (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 describes the core procedures that are required in respect to designing, monitoring and performing patient recruitment into research studies or trials. Exact procedures for identifying and approaching patients will be detailed in the study protocol (see PTUC SOP019: Research Protocol Design).

d. The subsequent gaining 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 and research studies hosted at or sponsored by 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 Papworth. They should be aware of the recruitment strategy and how recruitment is progressing. The Clinical Research Nurse or Trial Co-ordinator (CRN/CTC) and team members may be delegated the responsibility to keep records of patient recruitment and a screening 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 patient recruitment. These can be summarised as:

- identifying a potentially suitable patient
- screening the patient to ensure that they meet the inclusion and exclusion criteria
- obtaining informed consent from the patient
- enrolment in the study

b. The date of the signed consent of a patient will be the day that they are randomised or, if not randomised, the date they are consented onto the trial

c. Good Clinical Practice Regulations (2006) requires that records are kept of every patient that undergoes pre-trial screening i.e. details of all patients approached for a study should be maintained. For the purposes of this SOP, this shall be referred to as a screening log.

4.2 Recruitment Protocol

a. Before the first patient is enrolled a recruitment strategy should be planned and placed in the trial site file. All research staff working on studies must be familiar with the recruitment procedure. The PI and CRN/CTC should discuss this strategy with the Monitor (if a pharmaceutical study) or the Trial Organisers during the pre-study visit, or Trial Manager (Papworth Sponsored studies).

b. Other staff members working in the same disease area should be informed of each trial and encouraged to facilitate patient entry.

c. Recruitment goals should be set during study review and feasibility by estimation of likely patient numbers, and accounting for the length of the recruitment period. Recruitment targets should be realistic taking into account leave. The PI and the Monitor /Trial Organisers must be kept informed of the recruitment progress. Recruitment rates must be regularly assessed with the strategy being re-evaluated promptly if targets are not being met.

d. Staff involved in recruitment must be clearly identified on the study's Delegation Log (see R&D SOP030: Roles and Responsibilities/Delegation Log).

e. The delegated team member/s will keep a record of all patients who are approached about the study in a screening log. This will be kept confidential, but contain as a

minimum: the patient's initials, date of birth, date screened and if the patient was subsequently enrolled.

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

g. After enrolment, the patient's details will be added to a randomisation or enrolment log. As a minimum this will record: the patient's full name, date of birth, hospital number, study code or ID number, and the date of randomisation. Randomisation or enrolment logs must be stored securely.

h. The enrolment / randomisation log(s) must be archived at the end of the study as a record detailing all of the patients randomised in the trial, with patient name, year of birth and treatment allocation (if randomised). Refer to PTUC SOP011 Archiving.

i. This must be stored in secure accommodation 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: *Managment/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. Research Governance Framework for Health and Social Care (2005)
Key related documents:	Trust Research Policy [Insert list of linked or relevant documents to this SOP]

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 2019

Version Control

Version	Date effective	Valid to	Approved by	Date of approval
1.0				
2.0				
3.0				
4.0				

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

..... 15 Oct 2016

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

SOP release date: 18/10/16