Papworth Hospital NHS
NHS Foundation Trust

Document Title: Patient Recruitment

Document Number: SOP031

Staff involved in development: *Job titles only*	RM&G Manager, R&D Administration Manager, Research Officers
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Department:	Research and Development
For use by:	NHS Staff Trust-Wide
Review due:	October 2016

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 aims to provide clear 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

1.1 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.

1.2 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').

1.3 The document aims to describe 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 may vary from study to study and will be detailed in the study protocol (see SOP019: Research Protocol Design for Papworth Sponsored Studies).

1.4 The subsequent gaining of informed consent to participate in a research study is outside the scope of this SOP and is described in SOP003: Informed Consent.

2 Roles & Responsibilities

2.1 This Policy applies to all personnel that are conducting research at the Trust including: staff that are full or part-time employees of the Trust, those working at the Trust with employment contracts funded partially or wholly by third parties including those within Cambridge University Health Partners, Academic Health Science Centre and those seconded to and providing consultancy to the Trust, and to students undertaking training at the Trust.

2.2 Staff involved in the conduct of clinical trials and research studies performed at or sponsored by Papworth Hospital must comply with the requirements set out in section 4.

2.3 The Principal Investigator (PI) for each study within the Trust carries the primary responsibility 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

3.1 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

4.1.1 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

4.1.2 The date of the enrolment of a patient will be the day that they are randomised or, if not randomised, the date they are consented onto the trial

4.1.3 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

4.2.1 Before the first patient is enrolled a recruitment strategy should be planned. The PI and Clinical Research Nurse /Clinical Trial Co-ordinator 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).

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

4.2.3 Recruitment goals should be set at the start of the study by estimation of likely patient numbers, and accounting for the length of the recruitment period. For example, if you have estimated that you can enrol 20 patients into the study and the recruitment period is six months, you should enrol approximately four patients per month. Recruitment targets should be realistic taking into account planned and unplanned leave.

4.2.4 The CRN/CTC will be responsible for keeping records of patient recruitment and screening log. 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 when targets are not being met.

4.2.5 The exact procedure for patient recruitment should be detailed in the study protocol. All R&D staff working on studies must be familiar with the recruitment procedure. Staff involved in recruitment must be clearly identified on the study's Delegation Log (see SOP030: Roles and Responsibilities/Delegation Log).

4.2.6 When delegated, the CRN/CTC and team members 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.

4.2.7 Patient's informed consent should be taken according to SOP003 Informed Consent. 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.

4.2.8 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 inside a locked cabinet within a locked room.

4.2.9 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 SOP011 Archiving.
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

5.1 The R&D Department will ensure that this SOP, and any future changes to this document, are adequately disseminated.

5.2 The Unit 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 regulator agencies (*e.g.* Care Quality Commission, Medicines and Healthcare Regulatory Agency).

5.3 In exceptional circumstances it might be necessary to deviate from this SOP for which the 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.

5.4 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)*	8th November 2013
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 Research and Development Standard Operating Procedures entitled: SOP003: Informed Consent SOP011: Archiving SOP019: Research Protocol Design for Papworth Sponsored Studies SOP030: Roles and Responsibilities/Delegation Log

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 2016

Version Control

Version	Date Effective	Valid To	Approved by	Date of Approval
1.0		July 2011	RDD	04.09.2009
2.0	20th Dec 2013	October 2016	RDD	8th Nov 2013
3.0				