Document Title: Site Recruitment and Initiation

Document Number: PTUC SOP015

Staff involved in development: *Job titles only*	Senior R&D Manager, R&D Operational Manager, Research Officers
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Summary of Significant Change(s) (for this version only)

Section(s):	Modification:
All	Minor administrative changes throughout the document

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 and initiation of investigator sites (from now on referred to as 'sites') for research projects managed by Royal Papworth Trials Unit Collaboration (PTUC), sponsored by Royal Papworth NHS Foundation Trust or hosted by Royal Papworth NHS Foundation Trust.
- It provides guidance on the steps involved in the selection of sites, the assessment and initiation of a site, and who is responsible for obtaining the local approvals necessary for a study to commence, to ensure compliance with the Trust's policies.

1. Purpose and Contents

a. This document defines the Trust's procedures for the recruitment and initiation of sites for research projects managed by Royal Papworth Trials Unit Collaboration (PTUC), sponsored by Royal Papworth NHS Foundation Trust or hosted by Royal Papworth NHS Foundation Trust. This includes the selection of sites, approach, assessment and set-up.

b. The document describes who is responsible for the selection and recruitment of sites and obtaining local approvals.

2. Roles & Responsibilities

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

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

a. The following three steps must be performed:

1. Site Recruitment - this is the process of selecting appropriate sites (i.e. NHS Trusts) to participate in the study.
2. Site Approval - the process of obtaining the necessary approvals (regulatory, ethical, NHS R&D) for sites to participate in the study.

3. Site Initiation - this process ensures that all required trial documentation is in place and that the protocol and trial procedures are reviewed with the investigator and the investigator's trial staff in accordance with the protocol, SOPs, GCP, and the applicable regulatory requirement(s). Site initiation can be done in conjunction with site approval.

4.1 Site Recruitment

a. The Chief Investigator (CI) is responsible for selecting appropriate Principal Investigators (PI) and sites for a particular study although this task may be delegated to a member of the study team.

b. Once selected the potential PIs will be approached by the CI or member of the study team, to assess interest and willingness to participate in the study.

c. Each PI must demonstrate by education, training and experience that they are suitable to lead the study at their site and this must be evidenced in the form of current curriculum vitae (CV) stored in the trial master file (TMF). .

d. Once participation has been agreed in principle potential PIs and institutions are evaluated by the CI and study team to confirm their suitability. A pre-study visit may be necessary. The following must be assessed:

   1. qualifications and training requirements of the site staff
   2. potential to recruit suitable patients
   3. adequate facilities / equipment / resources to conduct the study

e. The site selection process and rationale for selection of a particular site must be documented and stored in the TMF.

4.2 Site Approval

a. Following confirmation of suitability as a site, the sponsor will provide the site with all the necessary documents and information to allow the site to:

   1. Assess their capacity and capability to participate in the study
   2. Obtain local R&D approval

b. All sites need to be listed on the Clinical Trials Authorisation (CTA) application (if appropriate) and Ethics application forms. For CTIMPs, addition of a site following submission of these forms is a substantial amendment (see PTUC SOP037: Amendments to Research Documents)

c. Sites will be requested to provide copies of the following documents:

1. Delegation log – a template delegation log will be provided by the sponsor for completion by the site. The individuals that need to be on the delegation log will vary from study to study but must include at least the PI.
2. CVs – for all individuals on the delegation log. Each CV must be current and signed/dated by the individual within the past 3 years.
3. Evidence of GCP training – for CTIMPs all individuals on the delegation log must have GCP training. Evidence must be a signed and dated copy of the GCP training certificate. GCP training must have been completed within the past 3 years. If training was over 3 years ago the individual needs to undertake appropriate GCP training prior to any study related activity
4. Laboratory normal ranges and accreditation certificates- for haematology and biochemistry laboratories (if appropriate to study).
5. R&D approval letter

4.3 Site Initiation

a. The CI is responsible for site initiation and this may be delegated to a member of the research study team.

b. Site initiation must be completed prior to the site opening to recruitment (before any trial related procedures are carried out). Initiation can be done in parallel with section 4.2.

c. For CTIMP and non-CE marked devices the initiation visit will be on-site. For other studies it can be performed remotely via tele-conference or e-mail although it may be necessary to visit the study site to complete the initiation process.

d. Each study activity covered in the initiation must be discussed with at least one member of the study team who has been delegated responsibility for the activity.

e. The PI must attend the relevant parts of the initiation and subsequently sign the front page of the study protocol. A copy of the signed protocol must be provided to the sponsor.

f. The following procedure should be followed for the initiation:

   1. Provide each site with a Site File. Ensure that investigators and other study team members are familiar with study requirements, adverse event reporting procedures, the relevant regulations, their roles and responsibilities
   2. Provide the site with the necessary documents, equipment and training to perform the required study related activities (i.e. Case Report Form (CRF) completion training)
   3. Milestones should be agreed
   4. Procedures regarding monitoring and auditing should be agreed

g. Site initiation visits must be documented and any issues raised addressed promptly (see Guidance Document GD002: Example Initiation Report Form, http://www.papworthhospital.nhs.uk/research/index/template-documents/). Documentation must include a site initiation check list to record the topics covered in the initiation process and the study specific training each member of staff received. Initiation reports will be reviewed by the trial manager and signed by the CI. A copy of the report will be provided to the site for filing in the Site File and a copy filed in the TMF.

4.4 Opening Sites to recruitment

a. The approvals must be in place, the initiation performed and the appropriate Regulatory Green Light (RGL) checklist (FRM023: RGL Checklist for Royal Papworth Sponsored Studies) form completed (forms available from R&D) prior to a site being open to recruitment. A copy of the RGL checklist form will be filed in the TMF.

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 approved version 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
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							

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Version Control

Version	Date effective	Valid to	Approved by	Date of approval
1.0		July 2011	RDD	
2.0	10 February 2012	February 2014	RDD	10 February 2012
3.0	20 December 2012	August 2016	RDD	8 November 2013
4.0				

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

..... 9th April 2019

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

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