DocuSign Envelope ID: CD769AC4-0157-4444-A8E2-1CFA80373156

Document Title: Site Selection and Initiation

Document Number: PTUC SOP015

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Department:	Research and Development
For use by:	NHS Staff Trust-Wide
Review due:	July 2024

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Summary of Amendments

Version:	Modification:
6.0	Minor administrative changes throughout the document

Key Points of this Document

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- This document 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 Hospital NHS Foundation Trust or hosted by Royal Papworth Hospital 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 four steps must be performed:

1. Site Selection - 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 (i.e., Trust Confirmation of Capacity and Capability)) and necessary documentation (e.g., Site Delegation Log etc), for sites to participate in the study.
3. Site Initiation Visit (SIV) - this process ensures that all required trial documentation for the study is in place and that the protocol and trial procedures are reviewed with the Principal Investigator and the investigator's trial staff in accordance with the

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protocol, SOPs, GCP, and the applicable regulatory requirement(s). The site initiation visit can be done in conjunction with site approval.

4. Sponsor Green Light – this final approval is issued by the Sponsor once the Sponsor is satisfied that all site approvals are in place, the site initiation visit has been completed, any issues raised at the SIV resolved and all site level study documentation is in place.

4.1 Site Selection

a. The Chief Investigator (CI) is responsible for identifying 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 identified, 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 a current curriculum vitae (CV) stored in the Sponsor File.

d. Once participation has been agreed in principle, potential PIs and institutions are evaluated by the CI and study team to confirm their suitability. This process is usually documented on a study feasibility questionnaire. 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 participants
   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 Sponsor File.

4.2 Site Approval

a. Following confirmation of suitability as a site, the sponsor will provide the site with the UK Local Information Pack which contains all the necessary documents and information to allow the site to:

   1. Assess their capacity and capability to participate in the study
   2. Issue local Trust Confirmation of Capacity and Capability

b. All sites need to be listed on the Ethics application form (i.e. the IRAS form).

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c. For CTIMPs all sites also need to be listed on the Clinical Trials Authorisation (CTA) application. The addition of a site following submission of the ethics application and/or the CTA is a substantial amendment (see PTUC SOP037: Amendments to Research Documents).

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

1. Site Delegation Log – a template site delegation log will be provided by the sponsor for completion by the site. The individuals that need to be on the site delegation log will vary from study to study but must include at least the PI.
2. CVs – for all individuals on the site 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 site 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. As above for any study specific training (e.g. device training). This may be completed at the Site Initiation Visit and recorded on the study training log.
5. Any localised study documents (e.g., patient information sheet).
6. Laboratory normal ranges and accreditation certificates for haematology and biochemistry laboratories (if appropriate to study).
7. Fully executed Site Agreement (signatures from all parties).
8. Formal receipt of Trust Confirmation of Capacity and Capability.

4.3 Site Initiation Visit

a. The CI is responsible for ensuring the site initiation visit is conducted. This responsibility may be delegated to a member of the research study team.

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

c. For CTIMP and non-CE marked devices the site initiation visit should be on-site. For other studies it can be performed remotely via tele-conference or e-mail (if deemed appropriate by the Sponsor).

d. Each study activity covered in the site initiation visit 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 site initiation visit and subsequently sign the front page of the study protocol. A copy of the signed protocol must be provided to the sponsor.

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f. The following procedures should be followed for the site initiation visit:

1. Provide each site with a Site File (if appropriate). 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 on GD002 (Example Initiation Report Form) which records the topics covered at the visit, study specific training each member of staff received and any issues raised or actions required. Any issues raised at the visit must be addressed promptly. The Site Initiation Visit 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 Sponsor File.

4.4 Sponsor Green Light

a. In order to open a site to recruitment, the site approvals and necessary documentation (e.g. Site Delegation Log etc) must be in place, the site initiation visit performed and Sponsor Green Light issued.

b. Sponsor Green Light should be issued by the Sponsor once the Sponsor is satisfied that all site approvals are in place, the site initiation visit has been completed, any issues raised at the SIV resolved and all site level study documentation is in place.

c. Sponsor Green Light should be notified to the site by email (see TPL037) including the R&D Governance team.

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).

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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.

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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 (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:	July 2024

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

DocuSigned by:
Dr Patrick Calvert
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06-Feb-2022

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

Date

Release Date: 14 FEBRUARY 2022