

## Document Title: Location Selection and Initiation

## Document Number: PTUC SOP015

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### Summary of Amendments

<b>Version:</b>	<b>Modification:</b>
6.0	Minor administrative changes throughout the document
7.0	Minor administrative changes throughout the document, document given an amended title. Reviewed for changes in regards to the new clinical trial R3 regs.

<b>Key related documents:</b>	SOP037: Amendments to Research Documents GD002 Initiation Report Form TPL037 Sponsor Green Light FRM098 Sponsor Green Light Checklist FRM100 Feasibility Questionnaire
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### Key Points of this Document

- This document provides guidance on the steps involved in the selection of locations (previously known as sites), the assessment and initiation of a research location, 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 selection and initiation of locations 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 approach, assessment and selection of locations and set-up in line with current NIHR metrics.
- b. The document describes who is responsible for the selection and initiation of locations 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 before a site can be opened to recruitment:
  1. Location Selection
  2. Location Approval
  3. Site Initiation Visit (SIV)
  4. Sponsor Green Light

## 4.1 Location 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 Sponsor team as per GCP.
- b. Once identified, the potential PIs will be approached by the CI or member of the Sponsor 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 Sponsor team to confirm their suitability. This process is usually documented on a study feasibility questionnaire (FRM100 Feasibility Questionnaire). A pre-study (Site Qualification) visit may be necessary. The following must be assessed:
  1. Qualifications and training requirements of the location staff
  2. Potential to recruit suitable participants
  3. Adequate facilities / equipment / resources to conduct the study
- e. The location selection process and rationale for selection of a particular location must be documented and stored in the Sponsor File.

## 4.2 Location Approval

- a. Following confirmation of suitability as a location, the sponsor will provide the location with the UK Local Information Pack which contains all the necessary documents and information to allow the location to:
  1. Formally assess their feasibility to participate in the study
  2. Issue local Trust Confirmation of Capacity and Capability
- b. All locations need to be listed on the Ethics application form (i.e. the IRAS form).
- c. For CTIMPs and Investigational Medical Device studies all locations also need to be listed as part of Combined Ways of Working (CWOW) application. The addition of a location following submission of the appropriate regulatory ethics application and/or the CWOW is a non-substantial modification (see PTUC SOP037: Amendments to Research Documents).
- d. Sites will be requested to provide copies of the following documents which must be saved in the Sponsor file:

1. Site Delegation Log – a template delegation log will be provided by the sponsor for completion by the location. 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 location’s delegation log. Each CV must be current and signed/dated by the individual within the past 3 years.
3. Evidence of GCP training – all individuals on the location’s delegation log should have GCP training (note this is a must for CTIMPS). Evidence must be a 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 refresher GCP training prior to any study related activity.
4. Evidence of study specific training (e.g. device training). This may be completed at the SIV 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 – Sponsor and participating site).
8. Formal receipt of Trust Confirmation of Capacity and Capability.
9. Confirmation that the SIV is complete – A SIV report (GD002) should be written and signed by the site’s PI and a member of the Sponsor team present at the SIV. Any issues raised at the SIV should be resolved prior to issuing Sponsor Green Light.

### **4.3 Site Initiation Visit**

- a. The CI is responsible for ensuring the SIV is conducted. This responsibility may be delegated to a member of the research study team.
- b. The SIV must be completed prior to the location opening to recruitment (before any trial related procedures are carried out). The SIV can be done in parallel with section 4.2.
- c. Each study responsibility, covered in the SIV, must be reviewed and delegated to at least one member of the study team who should be sufficiently qualified by education, training and experience.
- d. The PI must attend the relevant parts of the SIV and subsequently sign the front page of the study protocol (Protocol signature can be completed at a separate time if necessary). A copy of the signed protocol must be provided to the sponsor.
- e. The following procedures should be completed at the SIV:
  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 location 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 e.g. recruitment targets.
  4. Procedures regarding monitoring and auditing should be agreed.
- f. SIVs must be documented on GD002 (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 SIV report will be reviewed by the Trial Manager and signed by the PI and CI. A copy of the report will be provided to the location 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 location to recruitment, the location approvals and necessary documentation (as listed in section 4.2) must be in place, the SIV performed and Sponsor Green Light issued. FRM098 (Sponsor Green Light checklist) should be used to ensure all activities have been completed. If this form is not used a file note should be placed in the Trial Master File.
- b. Sponsor Green Light should be issued by the Sponsor once the Sponsor is satisfied that all location approvals are in place, the SIV 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 relevant site(s) 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).
- 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

<b>Approved by:</b> <i>Management/Clinical Group</i> <i>Directorate</i>		Research and Development Directorate					
<b>Approval date:</b> <i>(this version)</i>		Current approved version date					
<b>Ratified by Board of Directors/ Committee of the Board of Directors:</b>		STET					
<b>Date:</b>		N/A					
<b>This document supports:</b> <i>Standards and legislation</i>		Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care Research version 3.3 (07/11/17) and authorised amendments thereafter.					
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.							
<b>Groups</b>	Disability	Race	Gender	Age	Sexual orientation	Religious & belief	Other
<b>Yes/No</b>	NO	NO	NO	NO	NO	NO	NO
<b>Positive/Negative</b>							
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