Document Title: Roles and Responsibilities for the Conduct of Research Studies and Clinical Trials including CTIMPs (Clinical Trials of Investigational Medicinal Products)

Document Number: PTUC SOP055

Staff involved in development: *Job titles only*	Senior R&D Manager, R&D Operational Manager, Clinical Project Managers
Document author/owner:	Senior R&D Manager
Directorate:	Research and Development
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For use by:	NHS Staff Trust-Wide
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Summary of Amendments

Version Number	Modification:
Version 3.0	Administrative changes throughout

Key Points of this Document

- This document sets out the procedures to be followed by all Staff who Conduct Research Studies and Clinical Trials at Royal Papworth Hospital NHS Foundation Trust or research managed by Papworth Trials Unit Collaboration.

- It provides guidance on the Conduct of Research Studies and Clinical Trials to ensure compliance with the Trust's policies.

1 Purpose and Contents

a. This document defines the Roles and Responsibilities necessary for the conduct of Research Studies and Clinical Trials including CTIMPs (Clinical Trial of Investigational Medical Product) that are either managed by Papworth Trials Unit Collaboration, sponsored, or hosted by Royal Papworth Hospital NHS Foundation Trust.

b. This document details the Roles and Responsibilities of the Sponsor, Chief Investigator, Principal Investigator and other research staff as described in Good Clinical Practice

c. This document aims to provide clear guidance on who takes responsibility for each study process. It also provides information on the Standard Operating Procedures that should be consulted at each stage of a clinical trial.

2 Roles and Responsibilities

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

This SOP is mandatory and, as per the Trust's Information Governance and Records Management Framework, non-compliance may result in disciplinary procedures.

3 Procedure

The following sections outline the responsibilities of the key research parties.

3.1 Definitions

a. **The Sponsor** is the individual, company or an organisation and takes ultimate responsibility for the initiation, management and financing (or arranging financing) of the research study.

b. **The Chief Investigator** (CI) is the authorised health care professional who takes primary responsibility for the conduct of the research study. There is only one CI per country.

c. **The Principal Investigator** (PI) is the person who takes responsibility for the conduct of the research study at his/her site including the safety of all participants and the integrity and validity of the collected data. There should be one Principal Investigator at each site participating in a research study.

d. **All staff involved in a research study** take responsibility for the safety and well-being of research participants and for fulfilling the duties which they have signed up to on the delegation log.

3.2 Studies managed by Papworth Trials Unit Collaboration, or sponsored by Royal Papworth Hospital

a. All studies managed by Papworth Trials Unit Collaboration and Royal Papworth Hospital sponsored CTIMP and multi-centred studies must complete a Memorandum of Understanding (MoU) for Clinical Trial Delegation of Sponsorship Responsibilities (FRM028) **or the delegation of responsibilities should be specified in a collaboration agreement**. This authorises and details the agreed responsibilities of the Sponsor, PTUC and the Chief Investigator.

b. A Chief Investigator can also assume Principal Investigator responsibilities at their local site.

c. As stated in GCP guidelines an Investigator should be qualified by education, training and experience to assume responsibility for the proper conduct of a trial. They should meet all the qualifications specified by the applicable regulatory requirements and should provide evidence of such qualifications through up-to-date curriculum vitae (CVs should be dated and signed and no more than 3 years-old) and/ or other relevant documentation requested by the sponsor and regulatory authorities.

3.3 Project Management Delegation Log:

a. All studies managed by Papworth Trials Unit Collaboration, or sponsored by Royal Papworth Hospital should have a Project Management Delegation log (FRM042) that details the roles of all parties involved in the project management of the study. Project management of Royal Papworth sponsored studies is addressed in SOP009.

3.4 Non Royal Papworth Sponsored Studies (non-commercial)

a. Studies which are sponsored by a non-commercial party should have a memorandum of understanding (MoU) for Clinical Trial Delegation of Sponsorship Responsibilities which authorises and details the agreed responsibilities of the Sponsor, CI, PI and the participating site. The Sponsor may have their own version of an MoU, but in the absence of a Sponsor MoU FRM040 may be used and amended as required **or these maybe detailed in a collaboration agreement**

4 Delegation of Responsibilities:

a. **The Sponsor, Chief Investigator and Principal Investigator** may delegate certain duties, but the responsibility for ensuring that these duties are carried out remains with themselves.

b. **Responsibilities**

- Table 1 indicates who has **ultimate** responsibility for various tasks of a research study/clinical trial; the list is not exhaustive. For each study please refer to the MoU or Clinical Trial Agreement, delegation logs, the Good Clinical Practice guide and to study specific and/or local SOPs.

- The tasks in **bold** cannot be delegated.

c. **The Sponsor** can delegate all or some of their functions using the MoU but cannot delegate responsibility for the overall management of the research study.

d. **Delegation Log**: Each participating site will have a Site delegation log which will detail the roles and responsibilities of research staff as authorised by the PI.

6.1 Delegation logs

a. During the set up phase, the PI and the appropriate staff members' involved in the clinical trial, must discuss and agree on the study requirements with the Sponsor (or their delegated representative). The types of tasks that can be delegated will depend on the suitability of the individuals to perform the tasks.

b. The allocation of tasks should be recorded clearly in the Delegation Log. The PI should review the delegation log for each study and sign off each individual ensuring that they are:

1. Competent to perform the tasks that they have been delegated e.g taking informed consent, administering study medication.
2. Adequately informed about the protocol and investigational product(s).
3. Informed of their involvement and what duties they are expected to perform.

c. Each individual whose name is on the Delegation Log must sign and date their entry to acknowledge their given responsibilities for the trial. Individuals should only sign the log if they have received appropriate training in order to fulfil b.1-3 above. Each entry on the Delegation Log must be countersigned and dated by the PI.

d. The Delegation Log must reflect the current situation, showing what has been delegated to whom, with start and end dates. New staff must be added to the Delegation Log *after* being trained regarding the study protocol and their delegated tasks but *prior* to completing any study related activities. Further added responsibilities or changes to the above must be agreed by the PI and the Delegation Log must be updated accordingly. Corrections made with a single strike through, date and initials. This must be countersigned by the PI.

e. The Delegation Log must be stored in the Investigator Site File. CVs and GCP certificates must be available for everyone on the Delegation Log and stored in the Investigator Site File. Each CV must be current (within three years), signed and dated by the individual.

In addition for CTIMPS:

The Pharmacy Department delegation log is stored in the Pharmacy site file. A copy will be supplied to the Sponsor and both the original and the copy will be kept up to date throughout the study.

Table 1

Tasks	Sponsor	CI	PI	All Staff
Responsibility for the entire study/trial	**√**			
Responsibility for the research study at local site			**√**	
Delegation of duties at PI's site			**√**	
Sign off to say staff at PI's site are competent to work on a study			**√**	
Notification/submission of Regulatory Approvals e.g. HRA, MHRA, ARSAC, publicly accessible website and subsequent amendments	√	√		
Scientific Review	√	√		
Design and scientific/clinical validity of the protocol	√	√		
Development and dissemination of study documents e.g. patient information sheet, consent form	√	√		
Financing and insurance	√	√		
Contract negotiation and review	√			
Investigator/Site identification and initiation	√	√		
Monitoring	√			
Adverse event reporting	√	√	√	√
Preparation, submission of safety update reports	√	√		
Ensuring study appropriately funded at local site			√	
Investigational medicinal product/device: manufacturing, packaging, labelling, supply, written procedures	√			

Tasks	Sponsor	CI	PI	All Staff
Investigational medicinal product/device at PI's site: including- accountability, dispensing, storage.			√	
Randomisation procedure	√			
Randomisation and unblinding at PI's site			√	
Adequate resources at the PI's site e.g. time, participants, staff, facilities			√	
Compliance with the protocol	√	√	√	√
Trust specific approvals e.g. Directorate, Trust			√	
Safety reporting at local site			√	
Ensuring safety and well-being of all trial participants	√	√	√	√
Fulfilling the duties assigned on the delegation log				**√**
Completing GCP training				**√**
Maintaining training records				**√**
Alerting the PI or the CI or the Sponsor of any concerns that they may have regarding the conduct of the study				**√**

*Some SOPs apply to Royal Papworth sponsored studies only

5 Risk Management/Liability/Monitoring/Audit

a. The unit will ensure that this SOP and any future changes to this document are adequately disseminated

b. The Unit will monitor adherence to the 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 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.

d. The Research and Development Directorate is responsible for the ratification of this procedure.

PTUC SOP055: Roles and Responsibilities for the Conduct of Research Studies and Clinical Trials
Further Document Information

Approved by: *Management/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. 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:	January 2023

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

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

SOP release date: .....