Document Title: Roles and Responsibilities/ Delegation Log

Document Number: R&D SOP030

Staff involved in development: *Job titles only*	Senior R&D Manager, R&D Operational Manager, Clinical Project Managers
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For use by:	NHS Staff Trust-Wide
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Summary of Significant Change(s) (for this version only)

Section(s):	Modification:
	Minor administrative changes

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 Royal Papworth Trials Unit Collaboration.

- It provides guidance on the division and delegation of responsibilities and clarifies boundaries of responsibility and how they should be documented.

1 Purpose and Content

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 Royal Papworth Trials Unit Collaboration, sponsored, or hosted by Royal Papworth Hospital NHS Foundation Trust.

b. This document defines the Trust's research procedures for the documentation of the delegation of duties and responsibilities.

c. Delegation Logs are an essential document; identifying which individuals the Investigator has delegated study specific tasks.

d. In order for a study to adhere to Good Clinical Practice (GCP) guidelines, Study Protocol and applicable regulatory requirements it is essential that all staff involved are aware of their roles and responsibilities and that they are appropriate for the duties delegated to them by the Principal Investigator (PI).

e. The subsequent gaining of R&D permissions for a research study is outside the scope of this SOP and is described in SOP034: Trust Approval and Research Governance.

2 Roles & Responsibilities

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

b. **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.

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 (SOP030). It is the PI's responsibility to ensure that the Delegation Log is continuously up to date.

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 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 member state.

c. **The Principal Investigator** (PI) is the person who takes responsibility for the conduct of the research study at his/her site. 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.

5. Sponsor Delegated Roles and Responsibilities

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

a. All CTIMP and multi-centred studies sponsored by Royal Papworth Hospital must complete a Memorandum of Understanding (MoU) for Clinical Trial Delegation of Sponsorship Responsibilities (FRM028). This authorises and details the agreed responsibilities of the Sponsor (Royal Papworth) and the Chief Investigator.

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

5.2 Non Royal Papworth Sponsored Studies (non-commercial)

a. Studies which are sponsored by a non-commercial party and managed by Royal Papworth Trials Unit Collaboration 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, CTU 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.

6 Delegation of Responsibilities:

a. As stated in GCP 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.

b. The delegation log must reflect the current situation, showing what has been delegated to whom, with start and end dates. The PI must sign off each individual to show they are qualified by education, training and experience to perform their delegated duties. Evidence of appropriate training must also be included.

c. New staff must be added to the delegation log prior to completing any study related activities.

d. The Delegation Log must be stored in the Investigator Site File.

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

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 should ensure that all individuals are:

1. competent to perform the tasks that they have been delegated e.g Provision of training records: SOP002: Training Records.
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 needs to sign and date their entry to acknowledge their given responsibilities for the trial. Each entry on the Delegation Log must be countersigned and dated by the PI.

d. 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.

7 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.

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
Key related documents:	Trust Research Policy [Insert list of linked or relevant documents to this SOP]

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:	May 2022

Version Control

Version	Date effective	Valid to	Approved by	Date of approval
1.0				
2.0				
3.0				
4.0				

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

..... 16th July 2019

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

SOP release date: 22nd July 2019