York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
SOP
R&D/S110

PI Responsibilities

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

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Approved by:	Name/Position:	Monica Haritakis, Research QA Manager
	Date:	28th February 2023
	Name/Position:	Sarah Sheath, SOP Controller
	Date:	28th February 2023

This SOP will normally be reviewed at least every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Reviewers	Details of significant changes
1.0	28th March 2023	Jonathan Hawker Monica Haritakis	

Contents

1. Introduction, Background and Purpose

Under the UK Policy Framework for Health and Social Care Research & Clinical Trials Regulations, the role of Principal Investigator (PI) has clearly defined and prescribed responsibilities.

The PI takes responsibility for the conduct of the research at the site and must ensure that the research is conducted according to the approved protocol and in compliance with any applicable regulatory standards and guidance.

This SOP sets out the core responsibilities of PI's and outlines the steps to take if the PI has annual leave/sickness or is unable to fulfil their duties.

2. Who Should Use This SOP

This SOP is to be used by the Research Delivery Facilitators when setting up a study and by the Senior Research Nurses and Research Delivery Team in the event that a study PI is unable to fulfil their duties for a substantial amount of time.

3. When this SOP Should be Used

This SOP should be used when setting up new studies and in the event that a PI is unable to fulfil their duties for a substantial amount of time.

4. Procedure(s)

This process is to be used when setting up Clinical Trials of Investigative Medicinal Products (IMP), medical device studies and interventional studies.

1.1 Setting up new studies

During the process of setting up a new study the Research Delivery Facilitators (RDF) will identify a PI who will take responsibility for the conduct of the research at the site.

Any potential PI that expresses an interest or is invited to undertake the role will be asked to sign an agreement that outlines their responsibilities. It is the responsibility of the RDFs and the Research Delivery Team to obtain this agreement.

The prospective PI will need to respond to the email or sign the document confirming they have read and understood its contents. This agreement states that:

- The PI is fully aware of their responsibilities.
- Their research CV and GCP training are up to date and available upon request.
- They are responsible for all aspects of medical oversight of the study.

- If they cannot fulfil their PI role for more than 1 week, they must inform the Research Delivery Team so alternative arrangements can be made.

It is important that the PI is fully aware and understands their responsibilities. A clear line of communication between the PI and the study delivery team needs to be established and maintained through the duration of a studies lifetime.

All CTIMPS, device and interventional studies should appoint a Co-Investigator as standard. A Co-Investigator will provide stability in the event of a PI being unavailable. Ensuring that there will always be someone who has oversight available. The Co-Investigator will hold the same responsibilities as the PI and be subject to the same policies and procedures.

1.2 Process for ensuring PI understand and agrees to the responsibilities

- A potential PI is selected/ or expressed interests in taking role for a study.
- If there are any upcoming planned long-term absences these should be identified at this point to ensure suitability for the role and to ensure appropriate arrangements can be put in place.
- RDFs send template email (R&D/T44) or the delivery team can arrange to take a printed copy to the prospective PI directly. Either option is fine, but the prospective PI must acknowledge and agree to the contents.
- If the PI is unwilling to sign the agreement, they will not be able to proceed with the study.

At study set up and SIV the research governance procedures which are outlined in the R&D SOPs will be discussed and agreed.

2.1 Process where the PI is unable to undertake their responsibilities

There may be circumstances during the lifetime of a study which lead to the PI being unable to undertake their responsibilities. This may be the result of planned or unplanned leave. In these situations, this SOP must be consulted.

It is the responsibility of the PI to inform the R&D department via the research governance mailbox if they are not able to fulfil the PI role for a period longer than 1 week.

If the PI has given advanced notice of their inability to undertake their responsibilities the Senior Research Nurses must liaise with the PI about the situation to ensure that arrangements are put in place in time for that period.

If the inability of the PI to undertake their responsibilities is unplanned then the Senior Research Nurses must check with the PI regarding their current situation, if possible. If no response is received within 24 hours the Senior Research Nurses must escalate to the relevant Care Group Lead for Research.

The Care Group Lead for Research must email the relevant Care Group Manager. This email should contain the following options:

1. Arrange support for the PI in question and ensure that sufficient time and medical oversight can be dedicated to this project. Establish the reason and the timeframes for their unavailability so a short or long-term solution can be arranged.

2. If a lack of adequate oversight or communication takes place over a period longer than 3 months this must be communicated to the study sponsor and a replacement PI appointed as soon possible.

3. If a new PI cannot be identified within a week, then a temporary pause or premature closure of the study may need to be considered and communicated to Research Governance and the study Sponsor.

2.2 Types of cover

Short term cover

If short-term cover is required e.g., a PI is absent for more than one week, but less than four weeks then the study PI is responsible for confirming temporary arrangements with the R&D department for clinical oversight during the period of their absence.

R&D shall ensure that the appropriate cover is agreed with the current PI (e.g. sub-PI or Co-Investigator to temporarily take PI's responsibilities).

If no cover is available within the relevant CG, the Senior Research Nurses (SRNs) will raise the PI's oversight issue with the CG Research Lead to find alternative cover.

Study specific training (in study protocol and procedures) will be required. This must be confirmed and documented on the study Delegation Log and signed off by the current study PI.

Good Clinical Practice training may also be required depending on the type of the study (GCP is legally required for clinical trials of medicinal products or medical devices) – the R&D Team will be able to advise regarding this.

During the period of short – term absence/ unavailability, the study PI will retain overall responsibility for the conduct of the study.

Long term cover

Long-term cover is required when the PI is unavailable for longer than four weeks but less than three months.

The SRNs will liaise with the CG Research Lead and agree interim cover with the study sponsor.

The study Sponsor must be informed and temporary arrangements for PI cover confirmed in writing, appropriate training completed, and Delegation of duties Log signed.

During the period of long –term absence/ unavailability, the overall responsibility for the conduct of the study is delegated to the interim PI.

If no cover is identified, CG Research Lead will notify the CG Manager and/ or Clinical Director highlighting the importance of a research PI's responsibilities and medical oversight and request interim support from another clinician within the relevant CG.

If a new PI is not identified within a week, a temporary pause or premature closure of the study must be considered and communicated to R&D and the study sponsor.

5. Related SOPs and Documents

R&D/S37-Setting up new studies with your RDF and their Research Administrative Co-ordinator (RACo) (Research Teams)

R&D/S64-Setting-up Research Studies involving Imaging (including studies using Ionising Radiation)

R&D/S09-Set Up and Management of Research Studies

R&D/S04-Breaches of GCP or the Study Protocol

R&D/T44 – PI Agreement

6. Appendix A

Examples of PI Responsibilities

Applicable to all studies except where stated in square brackets. Some of these duties may be delegated to appropriately qualified and trained site staff.

TASK CATEGORY	TASK	PERSON / DEPARTMENT RESPONSIBLE	RELEVANT SOPS (see SOPs for related Forms and Templates)
Study Preparation	Identify and check equipment to be used for study	PI at Participating Site	R&D/S09
Applications and Registration	Obtain confirmation of Capacity and Capability at Sites	PI at Participating Site	R&D/S02 or R&D/S82 or R&D/S83
Study Conduct	Overall responsibility for work at Site – ensure it is done in accordance with the protocol, the Clinical Trial Regulations and / or Research Governance Framework and the terms of regulatory approvals.	PI at Participating Site	R&D/S09
	Ensure the rights of individual participants are protected and they receive appropriate medical care whilst participating in the study.	PI at Participating Site	
	Liaise with all involved support departments (e.g. pharmacy, labs) to ensure readiness at Participating Site	PI at Participating Site	R&D/S09
	Onward delegation of specific tasks; signing of delegation log	PI at Participating Site	R&D/S03 or R&D/S09
	Maintain Investigator Site File	PI at Participating Site	R&D/S09
Adverse events	Identify and document all adverse events	PI at Participating Site	R&D/S05
	Assess all adverse events	PI at Participating Site	R&D/S05
	Report all adverse incidents occurring in context of the study in accordance with the relevant NHS Trust's adverse incident reporting policy	PI at Participating Site	R&D/S05

Examples of PI Responsibilities

Applicable to all studies except where stated in square brackets. Some of these duties may be delegated to appropriately qualified and trained site staff.

TASK CATEGORY	TASK	PERSON / DEPARTMENT RESPONSIBLE	RELEVANT SOPS (see SOPs for related Forms and Templates)
	Notify R&D Unit of Serious Adverse Events using required notification method and within required timeframe	PI at Participating Site	R&D/S05
	Follow up Serious Adverse Events	PI at Participating Site	R&D/S05
	Implement an 'Urgent Safety Measure'	PI at Participating Site R&D Unit (Research Adviser or Head of R&D)	R&D/S68
	Report an 'Urgent Safety Measure' to MHRA [CTIMPs ONLY], the REC and the R&D Unit	PI at Participating Site	R&D/S68 R&D/S13
	Inform CI that an 'Urgent Safety Measure' has been taken at a Participating Site	PI at Participating Site	R&D/S68