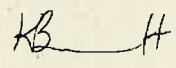



**STANDARD OPERATING PROCEDURE**  
**Delegation of Duties**

AUTHOR.	AUTHORISED BY	DATE AUTH	RISK MANAGEMENT PROCEDURE NUMBER
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		13-12-2024	

**RESEARCH AND INNOVATION**



**BACKGROUND**

At each trial or study site, a healthcare professional takes on the primary responsibility for the conduct and leadership of a trial or research study. In the UK, this individual is usually termed as an 'investigator'.

The 'investigator' is defined as 'the authorised health professional responsible for the conduct of that trial at a trial site, and if the trial is conducted by a team of authorised health professionals at a trial site, the investigator is the leader responsible for that team' (MHRA, 2012).

The investigator may be either a Chief Investigator (CI) for a single centre study or a Principal Investigator (PI) in a multi-centre study where the PI has responsibility for their own site activities.

The PI is responsible for the conduct of the trial or study and for the leadership of the trial or study team at their site.

**PURPOSE**

It is often impractical for the PI to deliver all elements of the trial or study at site so the PI may delegate activities to appropriate members of the research team. A delegation of duties log

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is a documented piece of evidence of the appropriate delegation of the investigator's responsibilities.

The purpose of this SOP is to explain the procedure for the appropriate delegation of duties by the trial or study investigator at Lancashire Teaching Hospitals NHS Foundation Trust.

## SCOPE

This SOP applies to all healthcare professionals involved in the delegation of duties of a research trial or study at Lancashire Teaching Hospitals NHS Foundation Trust. It specifically relates to the site investigator of the research trial or study and to those whom duties within a research trial or study are delegated to.

## PROCEDURE

### 1. WHO?

It is the responsibility of the site PI delegating study duties and the individual being delegated duties at Lancashire Teaching Hospitals NHS Foundation Trust to:

1. Have read and understood this SOP.
2. Undertake the procedure as per this SOP and the appropriate trial or study protocol.

Please note, that for a single centre, Lancashire Teaching Hospitals sponsored study, the PI duties below would be completed by the Chief Investigator.

### 2. WHEN

The site investigator must delegate activities prior to the activity being undertaken by the individual.

### 3. HOW

1. The PI may delegate activities to appropriate members of the research team.
2. The PI must ensure that the member of staff being delegated duties holds the appropriate qualification for the role they are to undertake (for example, medical degree or nursing qualification).
3. The PI must ensure the member of staff being delegated duties has been provided with appropriate GCP and protocol-specific training as well as any training necessary for the role / activity to be undertaken (for example, informed consent training or use on a particular piece of equipment). Evidence of appropriate training must be included in the site file (CV's / GCP certificates / training logs) and must be available for everyone on the delegation of duties log.

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4. The PI must ensure that all individuals are informed of their involvement and the duties required of them.
5. The PI must delegate trial or study activities on the delegation of duties log provided by the sponsor. If no log is provided by the sponsor then the investigator must use the Lancashire Teaching Hospitals delegation of duties log (RD-TMP-04 Delegation of Duties template available on the intranet - [Template Documents | Lancashire Teaching Hospitals Intranet \(lthtr.nhs.uk\)](#)). Please note that some delegation logs may be electronic, in which case, follow the instructions provided by the Sponsor.
6. The team member being added to the delegation log must clearly write their name full name (i.e. no initials or shortened nicknames), their role and the activities being delegated on the delegation of duties log.
7. All staff allocated will need to ensure they understand the roles allocated via discussion with the PI and review of the key on the delegation log.
8. The PI must sign and date the delegation of duties log prior to the activity being undertaken by the individual. i.e. the staff cannot start working on the study until the PI has signed the delegation log. It is not acceptable for the investigator to sign off the delegation log at the end of the trial or study.
9. The PI must ensure all study personnel are listed on the delegation of duties log (for example, co-investigators, and research nurses).
10. The investigator must not use a pre-signed delegation of duties log. The delegation of duties log must represent the current situation, with appropriate staff start/end dates, and not reconstructed retrospectively. The dates of entry must be in chronological order.
11. If new staff join the study team and will be working on the trial, the delegation of duties log must be updated. Likewise, if staff are no longer part of the team delivering the study, they must be signed off the delegation log prior to leaving.
12. Sponsors often ask for a copy of the delegation log. A copy also needs to be provided to pharmacy. Every time there are changes to the delegation log, a new version-controlled copy should be sent to pharmacy, and the sponsor if required.
13. It is the responsibility of the PI to ensure that the delegation of duties log is up to date. However, this can be delegated to the lead research nurse. They must keep the PI apprised of any changes to the delegation log in accordance with this SOP.
14. A sub-investigator must be listed on the delegation log and appropriately authorised by the PI to cover all PI duties in the event that the PI is not available.

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15. In the event that the PI is off on sick leave, it is the responsibility of the appropriately delegated sub-investigator to ensure that all PI duties are overseen appropriately. The sponsor must be informed, and a file note must be added to the site file to explain the PIs absence and confirm the appropriate level of cover is provided.

**4. OTHER RELATED PROCEDURES**

RD-TMP-04 Lancashire Teaching Hospitals NHS Foundation Trust Delegation of Duties Log

<b>Sign Off</b>			
<b>Lead Author:</b>			
<b>Name and Position</b>	Kina Bennett, Research Operations Manager		
<b>Signature</b>		<b>Date</b>	13-12-2022
<b>Reviewed and approved by:</b>			
<b>Name and Position</b>	Research & Innovation Committee Representative		
<b>Signature</b>		<b>Date</b>	13-12-2022
<b>Authorised for release by:</b>			
<b>Name and Position</b>	Rebecca Wilby, Research Access Project Manager		
<b>Signature</b>		<b>Date</b>	13-12-2022

<b>Controlled Copy Authorisation</b>			
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