UNIVERSITY OF LEEDS / NHS The Leeds Teaching Hospitals NHS Trust Standard Operating Procedure	Title	*Researchers Guide to appropriate Delegation of Duties for UoL / LTHT Sponsored CTIMPs*				
	Scope	Describes the process that the researcher follows when completing and maintaining a Delegation of Duties log for CTIMPs being sponsored by the LTHT / UoL				
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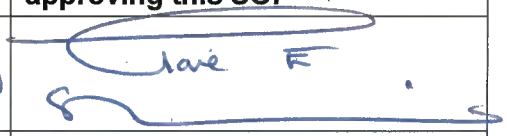
3.0	Clare Skinner, Head of Research Integrity & Governance	13/09/2019	
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Distribution & Storage:

Distribution to:

Investigators and all members of research teams conducting or assisting with a CTIMP trial sponsored by the University of Leeds or Leeds Teaching Hospital NHS Trust.

Location of document:

Paper: QA Department, Room 5, Research and Innovation Centre, St James' University Hospital
Electronic: http://www.leedsth.nhs.uk/research/information-for-researchers/key-documents
http://lthweb.leedsth.nhs.uk/sites/research-and-development/resources/Sponsored%20CTIMPs%20%28Quality%20Assurance%29

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Please note: *This SOP should be used and followed in conjunction with other UoL / LTHT SOPs developed for researchers to support study set up and management. These can be found on the LTHT website or by contacting R&I / QA directly. For clinical trials where Leeds is not the trial Sponsor, please refer to any Sponsor SOPs for further information.*

Section A: Introduction

1.1 This Standard Operating Procedure (SOP) outlines the procedure for the completion and maintenance of the Delegation of Duties Log / Authorised Signature Log for Clinical Trials of Investigational Medicinal Products (CTIMPs) being sponsored by the Leeds Teaching Hospitals NHS Trust (LTHT) or University of Leeds (UoL).

1.2 The Delegation of Duties Log / Authorised Signature Log is a mandatory document used to record the specific tasks delegated to each member of staff.

1.3 The Chief Investigator (CI) / Principal Investigator (PI) is permitted to delegate specific trial duties to the trial team, however oversight of all trial tasks must be maintained by the CI/PI.

1.4 The CI / PI of the trial have overall responsibility for the maintenance of the delegation log and overall trial conduct. The CI/PI can delegate tasks but not responsibility.

1.5 Each member of the team should perform their delegated duties adhering not only to this research guidance and relevant legislation, but also to local Trust and Professional Body requirements.

Section B: Applicability

1.1 This SOP is applicable to all Chief Investigators, Principal investigators, and all staff / researchers involved in the completion and maintenance of the Delegation of Duties Log / Staff Authorisation Log.

Section C: Researchers Guide to appropriate Delegation of Duties Log for UoL / LTHT Sponsored CTIMPS.

1. Delegation of Duties Log Requirements

1.1 For a trial to adhere to Good Clinical Practice (GCP) guidelines, trial protocol and applicable regulatory requirements, it is essential that all staff involved are aware of their roles and responsibilities and that they are appropriately qualified to undertake the duties delegated to them by the Chief Investigator (CI) / Principal Investigator (PI).

1.2 The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties (ICH GCP E6 4.1.6)

1.3 During trial set up, the CI/PI and the appropriate staff members involved in the clinical trial, must discuss and agree on the study requirements and all associated tasks.

1.4 The types of tasks that can be delegated will depend on the suitability and willingness of the individuals to undertake the role.

1.5 The resources available to the delegate and the capacity to satisfactorily complete the task must also be considered.

1.6 All trial specific tasks must be documented on a CTT09 Staff Authorisation and Responsibilities List / Staff delegation of duties log (hereafter known as Delegation Log). A template is available from the Sponsor QA office.

1.7 Should a department wish to use their own delegation log template, this must be agreed with Sponsor QA prior to trial commencement. This will usually take place during or prior to the initiation visit.

1.8 The allocation of tasks should be recorded clearly in the Delegation Log. The CI/PI should review the delegation log for each trial and should ensure that all individuals are:

- competent to perform the tasks that they have been delegated
- adequately informed about the protocol and investigational product(s)
- informed of their involvement and what duties they are expected to perform
- Evidence of appropriateness to perform the delegated duties is generally in the form of an up to date (within last 2 years) signed Curriculum Vitae (CV), and evidence of GCP training (refresher training every 2 years required) and any other training documents relevant to the delegated tasks.

2. Completing the Delegation Log

2.1 All headings throughout the document must be completed with trial information and CI/PI details.

2.2 A list of generic tasks is included on the bottom of the template log. The research team should discuss and agree if any additional trial specific tasks are required, and add them to the template log ('other' section). The CI/PI must review and approve each task to ensure the Delegation Log is fit for purpose.

2.3 All approved trial tasks must be delegated to at least one member of the Research Team.

2.4 Any additional tasks added to the log must be consistent on all Delegation Log pages.

2.5 If an additional task is identified whilst the trial is active, this must be added to all pages of the Delegation Log as per GCP (i.e. initialled and dated to ensure a full audit trail) and the task must be assigned to at least one delegate.

2.6 If a task is not required for the study e.g. 'Randomisation' for a single arm study, the task should be clearly marked as N/A (not applicable) on the task list.

2.7 Following discussion with the CI/PI each individual who will be working on the trial must enter their details on to the Delegation Log. This entry must be signed and dated by the individual to confirm their agreement to undertake the specified tasks. Each entry must then be countersigned and dated by the CI/PI before the member of staff can commence any trial specific activity. *MHRA GCP guide 11.3.4 states "It is not acceptable for the PI to simply sign off the Delegation Log at the end of the trial".*

2.8 More than one duty can be assigned to an individual given that he/she has the capacity and training to complete the assigned duties.

2.9 Further added responsibilities or changes to the above must be agreed by the CI/PI and the Delegation Log must be updated accordingly ensuring it remains fit for purpose. Corrections must be made with a single strike through, and dated and initialed as per *GCP E6 section 4.9.3.* Such corrections must be countersigned by the PI in real time.

2.10 If a member of staff leaves or is no longer working on the trial (or performing the delegated task), an end date must be added to the 'Date stopped work on trial' column. This must be completed in real time.

2.11 If during the course of the trial, there is a change in the CI and or PI, the current CI/PI must complete the end date column with their final date of working on the trial. The new CI/PI must then enter their information on a new line, entering their start date which should be the same date or the next day following the end date of the original CI/PI. The new CI/PI may specify in the 'Delegated tasks' column that he/she has taken on the tasks of the previous PI.

2.12 A change of CI/PI at a trial site is a substantial amendment. Please see "***QCRES_03: Researchers Guide to Notification of Amendments for Researchers for UoL_LTHT Sponsored CTIMPS***."

2.13 The Delegation Log must be stored in the TMF, and must be updated each time a new staff member is recruited or an existing staff member leaves.

3. Support Staff

3.1 Only the lead members of support departments (e.g. Pharmacy, Radiology, and Pathology) involved in the trial must be entered on to the main Delegation Log. A full list of the support department staff involved in trial specific duties will be listed on the signature log within the department. The lead member must take responsibility for all other staff within their department.

3.2 If a member of staff is only performing duties as part of standard care (e.g. a phlebotomist taking blood as part of a routine clinic, but an extra sample is taken for a research study), they are not required to be added to the Delegation Log.

3.3 If a member of staff is performing ANY trial specific task e.g. completion of the trial CRF, they **must** be entered on to the log.

4. Implementing a New Version of the Delegation Log

4.1 Prior to proceeding to use a new version of the Delegation Log, it is necessary that the previous log is shown to be no longer in use and cannot be further annotated.

4.2 All blank rows must have a strike through, initialed and dated to prevent further entry.

4.3 The previous log is NOT to be SUPERSEDED, the new log must be a continuous version, i.e. all entries from the previous log are not required to be re-entered or re-signed.

4.4 The new version must include all tasks from the previous log, if any tasks have been removed or added, this must be documented on the new log with clear explanation given.

4.5 The new version must be reviewed and signed by the CI/PI to confirm it is fit for purpose as per 2.7

5. Common Monitoring Visit / External Audit / MHRA findings

5.1 Poor completion of the Delegation Log is a common finding from Sponsor QA monitoring visits and MHRA inspections.

5.2 Common findings include but not restricted to;

- Tasks not being delegated appropriately - ALL listed tasks must be assigned
- Incomplete start and end dates - This must be updated in real time
- Signature columns not being signed - Member of staff is not permitted to undertake any trial specific activity until signed entry is complete and countersigned by the CI/PI (See 3.2.5).
- Failure to comply with GCP guidelines in correcting errors by initial and dating
- 'OTHER' tasks not always specified - ALL tasks and any additional tasks must be specified and assigned. This must be consistent on all delegation log pages.
- Members of staff included on the Delegation of Duties Log, however no CV and / or GCP found in TMF - Training documents for ALL staff listed must be held in the TMF.
- Presence of multiple Delegation Logs with different dates and details- See section 4 for correct procedure.
- Outdated CV / GCP documents - See 1.7
- The delegation log was reconstructed retrospectively; the dates of entries were not in chronological order. Therefore there was no evidence to demonstrate appropriate delegation prior to tasks being undertaken - See 2.5
- Key personnel were not listed on the delegation log, including sub-investigators involved in the clinical trial.
- The investigator site file contained logs pre-signed by the PI; therefore anyone could add their name and assign tasks, without appropriate review and delegation.

5.3 The Delegation Log will be monitored by QA during routine monitoring visits and will be checked for adherence to this SOP.

Section D: References

MHRA Good Clinical Practice Guide 2012
ICH GCP E6 4.1.6

Section E: Acronyms

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
ISF	Investigator Site File
LTHT	Leeds Teaching Hospitals NHS Trust
MHRA	Medicines and Healthcare products Regulatory Agency
PI	Principal Investigator
QA	Quality Assurance
SOP	Standard Operation Procedure
UoL	University of Leeds

Section F: Previous versions of Document

Version no.	Valid from	Approved by	Date approved
1.0	28/7/2016	Louise Brook, Clare Skinner	28/7/2016
2.0	27/4/2018	Louise Brook, Clare Skinner	23/05/2018