

Pharmacy Team – Signing onto the Study-Specific Delegation Logs

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THE CORRECT VERSION IS BEING USED**

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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	Details of significant changes
1.0	5 th November 2019	

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1 Introduction, Background and Purpose

This SOP has been created to help manage the process of signing onto the study-specific delegation logs of all relevant research studies that have pharmacy involvement in York Teaching Hospital NHS Foundation Trust.

Delegation logs are a requirement of Good Clinical Practice (GCP), which enable the Principal Investigator (PI) of a research study to delegate significant study-related duties to study staff members.

Pharmacy clinical trials staff members are not able to complete any delegated duties for a study (which may include for example, investigational product receipt or accountability), until they are signed to complete these duties on the study's delegation log and the PI has signed to approve their involvement.

Usually, the original, signed copies of the study delegation logs will be kept with the research team for each study speciality (for example the cardiology research team). However, an updated copy of the most recent study delegation log must be kept in the pharmacy site file (PSF), stored in the pharmacy clinical trials dispensary, so that this can be used as a checking tool for whether certain staff members are permitted to complete certain delegated duties.

Purpose:

- To create a spreadsheet that helps to support the process of signing onto the study-specific delegation logs, so that all actions related to this task are completed and all related documentation in the pharmacy site files is updated.
- To create a spreadsheet that acts as a reference tool for pharmacy staff members; which when maintained, will enable a quick view of the delegation logs that need to be updated in the event of a change in job roles.

2 Who Should Use This SOP

This procedure must be followed by all members of the Pharmacy clinical trials team, at York Teaching Hospital NHS Foundation Trust.

3 When this SOP Should be Used

This SOP should be used by all new starters in the pharmacy clinical trials team, once they have completed their GCP training and created a CV; in line with the Training of Pharmacy Personnel SOP (Pharm/S49).

A local copy of the "Delegated Duties List Master" spreadsheet (found on the pharmacy clinical trials x: drive) will need to be created and completed following the instructions in this SOP.

The master spreadsheet will need to be updated by an experienced member of the pharmacy clinical trials team before use, to ensure that new starters only sign onto the delegation logs of the current relevant studies. It will not be necessary to sign onto the delegation logs of any closed studies or existing open studies managed off-site with limited pharmacy involvement.

Once completed, the personalised, saved copy of the spreadsheet should be updated on a regular basis to take account of the staff member's involvement in any newly opened studies.

4 Procedure(s)

4.1 Create a local copy of the delegated duties spreadsheet

- Check that the “Delegated Duties List Master” spreadsheet has been updated recently by an experienced member of the pharmacy clinical trials team.
- Save a personal copy of the “Delegated Duties List Master” spreadsheet on your m: drive and edit this copy so that the master copy of the spreadsheet remains available.

4.2 Make appointments to sign onto the study-specific delegation logs

- Arrange appointments via email to sign onto the delegation log of each study listed in the spreadsheet. Use the “Common Contacts” document (found on the pharmacy clinical trials x: drive) to find the details of the correct person to contact to make each appointment (where this is usually the clinical trials assistant (CTA) for the study specialty).
- Requests should be made to sign onto multiple delegation logs at the same time where possible.

Only sign onto the delegation logs for the studies listed in the spreadsheet, as these will have been updated to the current open and pending trials requiring pharmacy involvement.

- Only select duties and tasks on the delegation log that are relevant to your role. Do not copy an entry from another person within the pharmacy clinical trials team as their duties may differ from your role in the study.
- Take a notebook to each meeting with the CTA or relevant research team member, in order to note down a list of the delegated responsibilities signed for on each delegation log.
- Meetings should take place with another member of the pharmacy clinical trials team, until confident of the delegated responsibilities to sign for.

4.3 Complete training and training logs for each study

- Training should be completed before signing onto the delegation log for each study (or on the same day) in accordance with Training of Pharmacy Personnel SOP (Pharm/S49).
- It will be necessary to complete a training log for each trial listed in the spreadsheet; either creating a new training log using form (Pharm/F61), or adding to an existing training log in Section 5 of the PSF where possible.
- Training must include at a minimum, the latest protocol and trial instructions for each study.
- Some studies may have study specific training which the sponsor requires you to complete. Check the PSF or contact the research team on how to complete this.
- IRT / IWRS access may be granted (if applicable to the study) following training and signing on to the delegation log. Contact the sponsor's CRA to gain access to the IRT / IWRS.

4.4 Update the spreadsheet and documents in the PSFs

- File the completed training log(s) in Section 5 of the study-specific PSF and update the relevant column in the spreadsheet to confirm that the training for each study has been completed.
- Update the spreadsheet after meeting with each CTA (or relevant research team member), to confirm the date each delegation log was signed and the list of responsibilities signed for.
- When the updated (PI-signed) copy of each delegation log is received, file this in Section 6 of the relevant PSF and supersede the old copy in Section 25.
- Complete the relevant columns in the spreadsheet to confirm when the PI-signed delegation log is received and when this has been updated in the pharmacy site file.
- Use the spreadsheet as a reference tool to chase any outstanding actions, until this task is fully complete.

5 Related SOPs and Documents

Pharm/S49 - Training of Pharmacy Personnel

Pharm/F61 - Pharmacy Training Record

“Delegated Duties List Master” spreadsheet (X:\Clinical Trials\Admin File\Assistant (ATO) Documents\Training and Induction)

“Common Contacts” document (X:\Clinical Trials\Admin File\Assistant (ATO) Documents\Training and Induction)

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