

Pharmacy Team – Signing onto the Study-Specific Delegation Logs

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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	Reviewers	Details of significant changes
1.0	5 th November 2019		
2.0	13 th February 2023	Dominic Burns Poppy Cottrell- Howe	Change of author
3.0	8 th June 2026	Angie Hewitt	Change of author Removal of the “Delegated duties list master spreadsheet” and “Common Contacts”

Contents

	<u>Page No</u>
1 Introduction, Background and Purpose	1
2 Who Should Use This SOP	1
3 When this SOP Should be Used	1
4 Procedure(s)	1
5 Related SOPs and Documents	3

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 and Scarborough Teaching Hospitals 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 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.

2 Who Should Use This SOP

This procedure must be followed by all members of the Pharmacy clinical trials team, at York and Scarborough Teaching Hospitals 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).

4 Procedure(s)

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

- The new starter should discuss with a member of the clinical trials team to establish which delegation logs they are required to sign and what their required duties are for each study, this will 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.

- Requests should be made to sign onto multiple delegation logs at the same time where possible.
- 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.

4.2 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.

4.3 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.

5 Related SOPs and Documents

Pharm/S49 - Training of Pharmacy Personnel

Pharm/F61 - Pharmacy Training Record

UNCONTROLLED DOCUMENT WHEN PRINTED