STANDARD OPERATING PROCEDURE FOR THE COMPLETION OF A DELEGATION LOG

SOP NUMBER:	TASC SOP023 v9
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1. PURPOSE

This Standard Operating Procedure (SOP) describes the procedure for completion of the delegation log to manage and document the delegation of duties to research staff in a clinical research study.

2. SCOPE

This SOP applies to clinical research studies sponsored or co-sponsored by the University of Dundee and/or NHS Tayside.

This SOP applies to Chief Investigators (CI), Principal Investigators (PI) and all staff who have been delegated duties in a clinical research trial.

3. RESPONSIBILITIES

Delegation Logs are mandatory for a Clinical Trial of an Investigational Medicinal Product (CTIMP) or as required by Sponsor.

Each participating location will have a delegation log detailing the research staff and their duties as authorised by the CI or PI.

It is the responsibility of the CI/PI to ensure that each individual on the delegation log is appropriately qualified for the role, has received GCP and study-specific training commensurate with the duties they have been delegated.

4. PROCEDURE

4.1.1 The CI/PI or delegate will review the Protocol and define Delegated Duties.

4.1.2 List the delegated duties on the Delegation Log. The list of duties must be specific to each study (please refer to Doc Ref 057). Each duty must be delegated to an appropriately trained member of the research team as evidenced in their training record.

4.1.3 Each member of the research team must add the following to the Delegation Log:

- Print Name & Title
- Signature and Initials
- Study Role
- Delegated Duties

Delegated duties should be written numerically and sequentially, i.e. 1, 2, 3, 4, not 1-4. The CI (if a single site) and PI must also be listed on the Delegation Log with key duties.

4.1.4 The CI/PI is required to sign and date the log for each individual to document the date key duties have commenced. The Delegation Log must be signed prior to individuals commencing any study-related duties. Individuals must only perform duties to which they have been delegated.

4.1.5 The CI/PI will be required to update the Delegation Log (sign and date) for each individual to capture when duties have ceased.

4.1.6 The Delegation Log must be held and maintained throughout the lifetime of a study in the Trial Master File (TMF) if a single site or Investigator Site File.

4.1.7 The Delegation Log is subject to monitoring and audit. It must be available for a monitor or auditor to confirm the suitability of the individual to the duties assigned, i.e. checks will be made to ensure that an individual has not been delegated a duty for which they are not trained.

5. ABBREVIATIONS & DEFINITIONS

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
PI	Principal Investigator
SOP	Standard Operating Procedure
TASC	Tayside Medical Science Centre
TMF	Trial Master File

6. ASSOCIATED DOCUMENTS & REFERENCES

Doc Ref 057: TASC Delegation Log

7. DOCUMENT HISTORY

History prior to 2021 is in the archived SOPs available from TASC Quality Assurance Dept.

Version Number:	Reviewed By (Job Title):	Effective Date:	Details of editions made:
7	Marney Keiller	23/09/2022	Biennial review no changes required.

	(Senior Clinical Trials Monitor)		
8	Marney Keiller (Senior Clinical Trials Monitor)	23/09/2024	Section 4.1.7 and Doc Ref 126 added to cover any difficulties when obtaining wet ink signatures.
9	Marney Keiller (Senior Clinical Trials Monitor	23/09/2026	Removal of section regarding when wet ink signatures are not possible and Doc Ref 126 added to cover any difficulties when obtaining wet ink signatures.

8. APPROVALS

Approved by:	**Date:**
Dr Steve McSwiggan, Senior R&D Manager NHS Tayside	18 Sept 2026
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	16 Sept 2026