



## STANDARD OPERATING PROCEDURE FOR COMPLETION OF DELEGATION LOG

SOP NUMBER:	TASC SOP023 v8
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### 1. PURPOSE

This Standard Operating Procedure (SOP) describes the procedure 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.

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

### 3. RESPONSIBILITIES

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

### 4. PROCEDURE

- 4.1.1 Review Protocol and define Key Tasks.
- 4.1.2 List the key delegated tasks on the Delegation Log (Doc Ref 057) and number each individually i.e. 1, 2, 3, 4, 5, not 1-5.
- 4.1.3 The list of key tasks must be specific to each project and can incorporate from the example list on Doc Ref 057.
- 4.1.4 Ensure that each of the tasks is delegated to an appropriately trained member of the research team as evidenced in the training record.
- 4.1.5 The Delegation Log must be complete prior to individuals completing any duties. Individuals should only complete duties to which they have been delegated.

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- 4.1.6 Two signatures from the CI/PI will be required for each individual, one to show when the task came into effect and the other to show when the duties ceased.
- 4.1.7 If a Delegation Log cannot easily be updated with wet ink signatures, please refer to the 'Delegation Log where wet signature not possible' (Doc Ref 126) which may be used to accompany the paper Delegation Log. It must be confirmed in advance that the use of Doc Ref 126 is acceptable to the Sponsor.
- 4.1.8 The Delegation Log must be held and maintained throughout the lifetime of a study in the Trial Master File (TMF) or Investigator Site File.
- 4.1.9 The Delegation Log is subject to monitoring and audit. It must be possible for a monitor or auditor to confirm the suitability of the individual to the task i.e. checks will be made to ensure that an individual has not been delegated a task for which they are not trained.

## 5. ABBREVIATIONS & DEFINITIONS

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
MHRA	Medicines and Healthcare Products Regulatory Agency
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

Doc Ref 126: Delegation Log where wet signature not possible

## 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 (Senior Clinical Trials Monitor)	23/09/2022	Biennial review no changes required.
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.

## 8. APPROVALS

<b>Approved by:</b>	<b>Date:</b>
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	18 Sep 2024