STANDARD OPERATING PROCEDURE FOR COMPLETION OF DELEGATION LOG

SOP NUMBER:	TASC SOP023 v7
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ISSUE DATE:	23 Sept 2022
EFFECTIVE DATE:	23 Sept 2022
REVIEW DATE:	23 Sept 2024

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 CTIMPs 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.

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

4.1.8 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	
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

7. DOCUMENT HISTORY

Version Number:	Reviewed By (Job Title)	Effective Date:	Details of editions made:
History of reviewers prior to 2014 is detailed in the archived SOPs			
3	Catrina Forde (Senior RGM) Adele Maxwell (Clinical Trials Monitor)	20/12/2014	Minor amendments for clarification purposes.
4	Tracy Petrie (TASC QA Support Officer)	07/09/2016	The title and the wording throughout this SOP have been changed from 'Delegation of Responsibilities' to 'Delegation of Duties'
5	Marney Keiller (Senior Clinical Trials Monitor)	23/09/2018	New TASC SOP format implemented. Change of title to 'Delegation Log'. Policy and procedure simplified. Now applicable to all clinical research studies. Removal of low and high-risk categories.
6	Marney Keiller (Senior Clinical Trials Monitor)	23/09/2020	Biennial review no changes required.
7	Marney Keiller (Senior Clinical Trials Monitor)	23/09/2022	Minor changes to Scope and Responsibilities sections for clarity.

8. APPROVALS

Sign			Date
APPROVED BY:		Professor Russell Petty, R&D Director, NHS Tayside	23rd September 2022
Signature	p.p.	Graeme Boyle	
APPROVED BY:		Dr Valerie Godfrey, TASC QA Manager, Chair of Clinical Research Guidelines Committee	23/09/2022
Signature		Valerie Godfrey	