

STANDARD OPERATING PROCEDURE FOR COMPLETION OF DELEGATION OF DUTIES AND SIGNATURE LOG

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1. PURPOSE

This document describes the procedure to be used by the Chief Investigator (CI), and Principal Investigator (PI) in multi-centre studies, to manage and document the delegation of duties to research staff and complies with the principles of Good Clinical Practice (GCP).

It is the responsibility of all researchers using this SOP to ensure they are using the latest version of it. The latest version is available via the Research & Development (R&D) pages on the NHS Fife Intranet (www.nhsfife.org/research) or for guidance, contact the R&D Office (fife-uhb.randd@nhs.net).

2. APPLICABILITY

This SOP applies to CIs, PIs and all staff involved in clinical research sponsored or co-sponsored by NHS Fife who have delegated duties.

For externally sponsored studies hosted by NHS Fife, the Sponsor's policies and procedures should be followed.

3. POLICY

- 3.1 For studies that are designated by the Sponsor as 'High Risk' (See SOP 07(Fife) – Risk Assessment), the CI must ensure that a Delegation of Duties and Signature Log Doc Ref 13-01) is held and maintained and that all staff named on the Log are qualified for their delegated role(s) by education, training and experience.
- 3.2 For all other types of clinical research, i.e. those designated as not 'High Risk' by the Sponsor, it is strongly recommended that a Delegation of Duties and Signature Log is put in place but this is not mandatory.
- 3.3 The Delegation of Duties and Signature Log is subject to monitoring and/or audit by the Sponsor.

4. PROCEDURE

- 4.1 The CI must ensure that duties which are delegated by him/her to members of a research team are documented on a study-specific Delegation of Duties and Signature Log (Doc Ref 13-01).
- 4.2 For multi centre studies, the PI at the local site must ensure that duties which are delegated by him/her to members of a research team are documented on a study-specific Delegation of Duties and Signature Log.

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- 4.3 The Delegation of Duties and Signature Log must be held and maintained by the CI/PI throughout the lifetime of a study in the Study Master File and Investigator Site File as appropriate.
- 4.4 All members of a research team who have agreed to accept delegated duties must be named on the Delegation of Duties and Signature Log (including the CI and PI where appropriate).
- 4.5 The specific delegated duties for each named person on the Signature and Delegation of Duties Log must be recorded by the CI/PI or delegate.
- 4.6 The CI and the delegate must sign, initial and date the Delegation of Duties and Signature Log when delegated duties come into effect. The date when delegated duties cease should also be recorded.
- 4.7 For multi-centre studies, the PI and the delegate at the local site must sign, initial and date the Delegation of Duties and Signature Log when delegated duties come into effect. The date when delegated duties cease must also be recorded.

5. ASSOCIATED DOCUMENTS

Doc Ref 13-01 - Delegation of Duties & Signature Log

6. ABBREVIATIONS

CI	Chief Investigator
GCP	Good Clinical Practice
PI	Principal Investigator
SOP	Standard Operating Procedure

7. REFERENCES

ICH E6 (R2) Good clinical practice
<https://www.ema.europa.eu/en/ich-e6-r2-good-clinical-practice>

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8. DOCUMENT HISTORY

Version Number:	Edited by (job title):	Effective Date:	Details of Revisions Made:
1	Linsey Burd R&D Research Nurse	10/11/2014	New - adapted from TASC SOP23, Version 2.0, 20/12/2012
2	Julie Aitken R&D Trials Facilitator	09/11/2017	Format amended for consistency with NHS Fife SOP template. Title and wording throughout changed from 'Delegation of Responsibilities' to 'Delegation of Duties'. Clarified that this SOP refers to NHS Fife sponsored studies.
3	Julie Aitken R&D Quality & Performance Lead	15/07/2020	Format amended for consistency with current SOP template. Reference to CTIMPs removed as NHS Fife does not sponsor CTIMPs.

9. APPROVAL

APPROVED BY	Date
Professor Alex Baldacchino, Research, Development & Innovation Director, NHS Fife Signature: 	15 July 2020

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