# SOP: Delegation log

| Version | Author(s) | Date | Changes | Approved by |
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| 1.0 | Johanne Juul Petersen<br>Mathias Lühr Hansen<br>Caroline Kamp | 13/11-24 | Initial version | Steering Committee |

## Content

## Why should the principal investigator keep a delegation log?

To comply with the guidelines of the International Council for Harmonisation of Technical Requirements For Pharmaceuticals For Human Use: Good Clinical Practice (ICH-GCP), all principal investigators must fill out a delegation log (see 'Delegation log template' on www.safeboosc.eu under 'SOPs and templates' ). The purpose of this log is to ensure that all staff members involved in the care of trial participants are properly trained to do so. By signing the delegation log, staff members document that they have been informed about the trial, their tasks, and that they have received sufficient training to conduct their trial-related tasks (e.g. individual web-based training, group training, read-through of training material and cases).

## How to create a delegation log

The delegation log includes the following: 1) the list of staff members potentially involved in the care of trial participants and their signatures documenting that they comply with the criteria stated in the section above, and 2) a description of trial-related tasks for all clinical positions (see 'Template for description of trial tasks for staff members' below).

### List of staff members and dated signatures

*Screenshot of a delegation log*

| Clinical position | Name | Type of training and/or education to ensure sufficient theoretical knowledge and practical skills to conduct trial tasks (insert number(s))<br><br>1 = Web-based training<br><br>2 = Group training/education based on available material on safeboosc.eu<br><br>3 = Individual training/education based on available material on safeboosc.eu | Signature | Date |
|---|---|---|---|---|
| Nurse | John Doe | 1 |  | 26.10.2024 |

The principal investigators must follow the steps below to prepare and fill out the delegation log:

1) Identify the names of all nurses and doctors potentially involved in the care of trial participants.
2) Download the 'Delegation log template' from www.safeboosc.eu under 'SOPs and templates' and fill in all names and clinical positions as per the example above.
3) The principal investigator must then ensure that staff members sign the delegation log. To minimise work, we suggest printing the delegation log, hanging it somewhere central in the department, and informing staff members of its presence.

When signed, the delegation log must be kept in the Investigator Site File (ISF). The principal investigator must regularly update the delegation log when new staff members are included in the care of trial participants. The principal investigator must inform new staff members of the trial and have them sign the delegation log, once they have received training to ensure sufficient theoretical knowledge and practical skills to conduct trial tasks.

During initiation and monitoring visits, the local monitor person will continuously monitor the percentage of staff members that have signed the delegation log.

## Description of trial tasks for staff members

This chapter serves as an example on how to organise and describe trial-related tasks among staff members on duty. If feasible, it can be done as a group delegation, i.e. a description of trial tasks for each group of clinicians. The description of trial-related tasks must be documented in the delegation log (see 'Delegation log template' under 'SOPs and templates' at www.safeboosc.eu).

*Example of group-delegated tasks*

Doctor

The doctor on duty is responsible for the following:

- Enrolment of new trial participants (see 'SOP: Enrolment and randomisation' in the ISF or on www.safeboosc.eu 'SOP and templates').
- Treatment of trial participants according to the treatment guideline (see 'SOP: Treatment guideline' in the ISF or on www.safeboosc.eu).
- Registration of serious adverse reactions (SARs) in the electronic Case Report Form (eCRF).

Nurse

The nurse on duty is responsible for the following:

- Practicalities in regards of NIRS monitoring (see 'SOP: NIRS device and sensor handling' in the ISF or on www.safeboosc.eu 'SOP and templates').