SOP: Delegation and Training log

Version	Author(s)	Date	Changes	Approved by
1.0	Mathias Lühr Hansen	16.01.19	Initial version	Gorm Greisen

Content

1.0 Why should the PI keep a delegation and training log?

All principal investigators must fill-out a delegation and training log (see "Delegation and Training log template" on www.safeboosc.eu). The log serves two purposes; 1) for the trial to be conducted in compliance with the guidelines of the International Conference on Harmonisation Good Clinical Practice, and 2) to monitor the proportion of staff members from each NICU that have signed the log, as documentation that they have been informed about the trial and the web-based training and certification program.

2.0 How to create a delegation and training log

The delegation and training log includes two things: 1) the list of staff members potentially involved in the care of trial participants, and their signature documenting, that they have received information on the trial, their tasks as written at the delegation log (see 2.2), and the web-based training and certification program (see 2.1), and 2) a description of trial related tasks for all clinical positions (see 2.2).

2.1 List of staff members, signatures and web-ID

Screenshot of a delegation and training log

Clinical position	Name	Signature	Date
Nurse	James Miller	[illegible]	3/3 19
Nurse	Beth O'connor		
Doctor	Sarah Huntsby		
Doctor	Toby Grant		

The PI must follow the steps below to prepare and fill-out the delegation log

1) Identify the names of all nurses, doctors (and radiologists) potentially involved in the care of trial participants
2) Download the "delegation and training log template" from www.safeboosc.eu under the column "SOPs" and fill in all names and clinical positions as per example above.
3) Send an e-mail to mathias.safeboosc@gmail.com with the total number of nurses, doctors and radiologists respectively. This will be used to monitor the certification process and report this to the PI.
4) PI must then ensure that staff members sign the log (see 2.0). To minimize work for PI's, we suggest printing the delegation and training log out, as per example above, hang it somewhere central in the department and inform staff members of its presence.

When signed, a copy the delegation and training log must be kept in the TMF. The PI must regularly update the delegation and training log, when new staff members are hired in the department, inform them of the study and existence of the web-based training and certification program, and have them sign the delegation and training log.

The GCP person will monitor the percentage of staff members that have signed the log continuously at initiation and monitoring visits.

2.2 Template for description of trial tasks (group delegation) for staff on duty

This chapter serves as an example on how to organize and describe trial related tasks among staff members on duty. It should 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 and training log (see “delegation and training log template” under “SOPs” at www.safeboosc.eu).

Example

Doctor

The doctor on duty are responsible for the following

- Enrollment of new trial participants (see SOP: enrollment and randomisation in the TMF or on www.safeboosc.eu)
- Treatment of trial participants according to the treatment guideline (see SOP: treatment guideline)
- Registration of SAR’s in the clinical files

Nurse

The nurse on duty are responsible for the following

- Practicalities in regards of NIRS monitoring (see SOP: NIRS device and sensor handling)