Report on initiation at investigator site

Protocol	SafeBoosC III trial			
Site				
Sponsor	Gorm Greisen, Rigshospitalet			
Investigator			**Date of visit**	
Participants	***Name (initials)***	***Role***	**Report date**	
	From site:			
	GCP person:			

1. Completion of Trial Master File	**Yes**	**No**	**Was not checked**
1.1 Is there a Trial Master File available, including documents as required per GCP monitoring plan? (if any missing, please comment)	☐	☐	☐
Comments:			

2. Number of clinical staff members signed for being informed on the trial, their tasks as written in the delegation and training log, and the web-based training and certification program	**Number of clinical staff members**
2.1. What is the number of clinical staff members that have signed for being informed on the trial, their tasks as written in the delegation and training log, and the web-based training and certification program?	
2.2. What is the total number of clinical staff members on the delegation and training log?	

3. Blinding procedure of cranial ultrasound readings and data entry	**Yes**	**No**	**Was not checked**
3.1. Has the principal investigator demonstrated the local blinding procedure for diagnosing severe brain injury on cranial ultrasound and data entry?	☐	☐	☐
Comments:			

Points for follow-up			
Date	**Follow-up**	**Respon-sibility**	**Com-pleted**

Signatures

This report has been prepared by:

_____ _____

Date

GCP person

As Sponsor Investigator I have reviewed the report and assumes responsibility for any follow-up:

_____ _____

Date

Sponsor Investigator

As Principal Investigator I have reviewed the report and assumes responsibility to handle any follow-up until the next GCP visit.

_____ _____

Date

Principal Investigator

A copy of the signed report is archived in the Trial Master File of the trial. The original is sent to the Sponsor Investigator