GCP Report on monitoring at investigator site

Reviewed trial subjects' study ID's (type below)

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

1. Information in clinical files/records and signed consent	**Yes**	**No**	**Was not checked**
1.1. Is there a clinical file/record on each of the reviewed trial subjects?	☐	☐	☐
1.2. Is participation in the trial documented in the clinical files of each reviewed trial subject?	☐	☐	☐
1.3. Is there a signed consent form (single or both parents as required by local regulations) with a date before the intervention (if deferred consent is used, the signature can be after the time of intervention) or if 'opt'out' method is used, documentation in clinical file of trial participation, that parents have been informed and their response, for each of the reviewed trial subjects?	☐	☐	☐
If any deviations, please comments:			

2. Source data verification	Yes	No	Was not checked
2.1 Is there agreement between the clinical file and eCRF regarding group allocation, for each of the reviewed trial subjects?	☐	☐	☐
2.2 Is there agreement between the clinical file and eCRF regarding gestational age lower than 28 weeks, for each of the reviewed trial subjects?	☐	☐	☐
2.3 Is there agreement between the clinical file and the eCRF regarding mortality, for each of the reviewed trial subjects?*	☐	☐	☐
If any deviations, please comment:			

*Please recall that subjects should only be registered as "Dead" if the event occurred before 36 weeks of postmenstrual age. If death occurs later, the subject should be registered as "Alive".

3. Delegation and training log	Number of clinical staff members
3.1. 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?	
3.2. What is the total number of clinical staff members on the delegation and training log? Divide in nurses/neonatologists/radiologists	/ /
Comments:	

4. Check of patient inclusion list	Yes	No	Was not checked
4.1 Is the patient inclusion list completed, i.e. personal identifiers and study-ID on all patients?	☐	☐	☐
4.2 Does the study ID's on the patient inclusion list match the study-ID's registered in the eCRF?	☐	☐	☐

4. Check of patient inclusion list	Yes	No	Was not checked
If any deviations, please comment:			

5 Issues for follow-up from last visit	Yes	No
5.1. Were there any issues for follow-up at last monitoring visit?	☐	☐
5.2. If yes to '5.1', have the issues for follow-up been resolved?	☐	☐
If 'No' to 5.2, please specify below, which issues for follow-up that was not resolved and transfer them to this monitoring visits 'Issues for follow-up'.		

Next scheduled visit:	

Issues for follow-up		
Date	**Follow-up**	**To be performed by**

Signatures
This report has been prepared by:

_____ _____

Date

GCP person

As Principal investigator I have reviewed the report and assumes responsibility for any follow-up:

_____ _____

Date

Investigator

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

_____ _____

Date

Sponsor Investigator, Gorm Greisen

The signed report is archived in the investigators Trial Master File.