SOP: Clinicians reporting adverse events

Version	Author(s)	Date	Changes	Approved by
1.0	Maria Skoog Anne Mette Plomgaard	29.05.12	Initial Version	Gorm Greisen
1.1	Maria Skoog Anne Mette Plomgaard	19.07.12	Minor changes	Gorm Greisen

CONTENT

1.0 Serious or suspected serious adverse events

Events not considered related to the intervention are not to be reported!

Serious adverse events are to be assessed at 3, 6, 24, and 64 hours and at 7 days. (According to the protocol death and morbidity not related to the intervention are reported as outcome measurements)

1.1 How do I report a serious adverse reaction/serious device effect?

These must be *reported to sponsor within 24hours*. The events are reported in the eCRF, thereafter printed and faxed.

The procedure:

- Open the eCRF
- Choose: *Serious AE*
- Fill in the information required *(see **Appendix A)***
- Press save
- Press the print-icon
- Print the Coverpage: ***Appendix B***
- Fax the printed Appendix B and the printed version of the eCRF to sponsor within 24 hours:

  Professor Gorm Greisen
  Neonatalklinikken
  Rigshospitalet
  Blegdamsvej 9
  DK-2100
  Denmark

Fax number: +45 3545 5025

- Call sponsor Gorm Greisen at **+45 3545 1326 or +45 4046 0747** and inform about the incidence

- Save the original report for the GCP-monitor

- *Report the incidence to your local Ethic Committee according to national guidelines.*

Sponsor is according to protocol responsible for reporting the event to relevant national competent authorities.

What if the eCRF is unavailable?

- Print Appendix A or the SafeBoosC offline CRF
- Fill in the information required
- Print Appendix B, Coverpage and fax the information as described above

1.2 What is a serious adverse reaction/serious device effect?

An event that is related/suspected related to the intervention and:

- results in death
- is life-threatening
- requires prolongation of existing hospitalization
- results in persistent or significant disability, incapacity or requires intervention to prevent permanent impairment or damage

1.3 Which serious adverse reactions/serious device effects must be reported?

Device deficiencies: malfunction, misuse, or use error **-** if potential serious effect
SAE-NI: serious adverse event-near-incident
ESAR/ESADE: expected serious adverse reactions / expected serious adverse device effect
SUSAR/USADE: suspected unexpected serious adverse reaction / unanticipated serious adverse device effect

For definitions see *Appendix C*.

2.0 Expected or unexpected non-serious adverse events

Events not considered related to the intervention are not to be recorded!

Non-serious adverse events are to be assessed at 3, 6, 24, and 64 hours.

2.1 How do I rapport an expected or unexpected not-serious adverse reaction/not-serious device effect?

These events are reported in the eCRF (non-serious AE). The events are required data, and we recommend that this part of the eCRF is filled in at the end of the intervention period.

The procedure:

- Open the eCRF
- Choose (non-serious AE)
- Fill in the required information
- Press save

(Sponsor is according to protocol responsible for reporting the expected/unexpected not-serious events to the national competent authorities at the end of the trail.)

2.2 Which expected or unexpected non-serious adverse reactions/non-serious device effects are reported?

EAR/EADE expected adverse reactions / expected adverse device effect
UAR/UADE unexpected adverse reactions / unexpected adverse device effect
Device deficiencies: malfunction, misuse, or use error – not potentially serious effect.

For definitions see *Appendix C.*

Appendix A

eCRF - clinicians reporting serious adverse event

Parient ID: _____

Patient, date of birth: _ _ / _ _ / _ _ _ _

Investigator/name of the person reporting the event:
_____

Which event is being reported?
Only one can be chosen

Device deficiencies with potential serious effect □
SAE-NI □

Serious adverse event-near-incident
ESAR □
Expected serious adverse reactions
ESADE □
Expected serious adverse device effect
SUSAR □
Suspected unexpected serious adverse reaction
USADE □
Unanticipated serious adverse device effect

This rapport is:

Initiating rapport □
Follow up rapport □
Final rapport □

Medical device

Which Medical Device was used:

Covidien, INVOS-oximeter, with Adult SomaSensor (SAFB-SM) □
Hamamatsu, NIRO-200NX with Prope holder S type (A10963) □

Was the event related to the Medical device – (NIRS-monitor)?

Yes □
Possibly □
No □
Do not know □

THE EVENT

When did you become aware of the event?

Date and time: _ _ /_ _/_ _ _ _, _ _:_ _

Has the event ended? **Yes** □ **No** □

If yes, when did the event end?

Date and time: _ _ /_ _/_ _ _ _, _ _:_ _

Description of the event:

_____
_____
_____
_____
_____
_____

Category of the event:
More than one X is accepted. No X should be made if a SAE-IN is being reported.

Death	□
Life-threatening illness or injury	□
Prolongation of existing hospitalization	□
Permanent impairment of a body structure or body function	□
Necessity of medical or surgical intervention to avoid above mentioned	□

Was any action taken on the event? **Yes** □ **No** □

If yes describe:

_____
_____
_____
_____
_____
_____

Event status:

Resolved	□
Resolved with sequelae	□
describe:_____	
Ongoing	□
Death	□

Appendix B - Coverpage

HASTER:
DENNE FAX SKAL VURDERES INDEN 24 TIMER!

SERIOUS ADVERSE EVENT SafeBoosC

Denne fax skal vurderes af Gorm Greisen indenfor 24 timer

Gorm Greisen kan kontaktes på telefon 3545 1326 / 4046 0747

Hvis ikke Gorm Gerisen er tilgængelig, skal faxen leveres til PhD-studerende Simon Hyttel-Sørensen eller Anne Mette Plomgaard.

Simon: 2812 4036
Anne Mette: 2858 8929

Appendix C

Definitions:

Adverse events (AE): any undesirable event occurring to a participant during a clinical trial, whether or not considered related to the trial intervention.

Serious adverse event (SAE): any adverse event that results in death, is life-threatening, requires prolongation of existing hospitalisation, result in persistent or significant disability or incapacity, or requires intervention to prevent permanent impairment or damage.

Adverse reactions (AR) / Adverse device effects (ADE): all untoward and unintended responses related to the interventions of application of the treatment guideline and/or cerebral oximeter.

Expected adverse reactions (EAR) / Expected adverse device effect (EADE): adverse reactions, we expect to be related to the interventions cerebral NIRS oximeter and/or the application of the treatment guideline.

Unexpected adverse reactions (UAR): All untoward and unintended responses, which are not, expected reactions, related to the interventions cerebral oximeter and/or application of the treatment guideline.

Serious adverse reactions (SAR): any adverse reaction that results in death, is life-threatening, requires prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or requires intervention to prevent permanent impairment or damage. This definition includes:

Serious adverse device effect (SADE): adverse device effect that has resulted in any of the consequences characteristic of a SAE, or are due to imprecise or incomplete results from diagnostic equipment e.g. incorrect or delayed diagnosis or incorrect or delayed treatment, and

Serious adverse effect-near-incidents (SAE-NI): device deficiencies that might have led to a SAE if a suitable action had not been taken, or intervention had not been made, or if circumstances had been less fortunate.

Expected serious adverse reactions (ESAR): any of the expected adverse reactions (listed above) that results in death, is life-threatening, requires prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or requires intervention to prevent permanent impairment or damage.

Suspected unexpected serious adverse reaction (SUSAR) / Unanticipated serious adverse device effect (USADE): an adverse reaction which is both serious and unexpected, i.e., not identified in the current risk analysis listed above (in expected adverse reactions). Included in this definition are the events with imminent risk of death, serious injury, or serious illness that requires prompt remedial action for other participants, users, or persons (including events that are of significant and unexpected nature such that they become alarming as a potential public health hazard or the possibility of multiple deaths occurring at short intervals) or a new finding to the event.

Device deficiencies: malfunction, misuse, or use error, e.g. rStO2 values displayed despite displaced sensor, sensor positioned with light source facing away from skin surface, sudden malfunction of device that result in no or false rStO2-values.