

SafeBoosC CRF trail

Version 1.4

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Janus Engstrøm

Copenhagen Trial Unit

Version 1.0	Initial version
Version 1.1	Added "MRI", updated "Compliance", updated CRF names and -order
Version 1.2	Changed "Ultrasound scan", added link to SOP webpage to "Screening", "Randomisation", "Intervention", "Ultrasound scan", "aEEG / EEG", "MRI", "Adverse Events", "Serious Adverse Events"
Version 1.3	Minor textual change in "Screening form"
Version 1.4	Split questions and changed response set in "Ultrasound scan". Textual changes in "Intervention form"

Screening Form

- CRF draft version 6 released to CRF final version 1

Versions after initial release	Reason for change	Note
Version 2 Release date: 06-06-2012	a. Changed (S.02) into two fields to allow collection of gestational age in measured in weeks and days b. Added (S.04) to allow collection of birth weight	Data from Version 1 CRF deleted and re-entered into Version 2, Version 1 disabled
Version 3 Release date: 03-12-2012	Changed the text in (S.01) from "Screening date" to "Date of birth"	

Randomisation Form

- CRF draft version 2 released to CRF final version 1

Intervention Form

- CRF draft version 9 released to CRF final version 1

Versions after initial release	Reason for change	Note
Version 2 Release date: 08-06-2012	(S.27) changed in wording to "At 64 hours [...]"	Data from Version 1 CRF deleted and re-entered into Version 2, Version 1 disabled
Version 3 Release date: 30-06-2012	a. Added a "no information" option to all response sets b. Removed (S.25) concerning biomarkers at time of birth c. Added (S.28), (S.29) and (S.30) regarding duration of NIRS monitoring and reason for prematurely stopping NIRS monitoring	Data from Version 2 CRF deleted and re-entered into Version 3, Version 2 disabled
Version 3 revised	a. (S.27) changed in wording to "10^9/l" b. (S.31) changed in wording to "Adverse Reaction / Device Effect occurred" and information about AE registering change to a more verbose form	

Compliance

- CRF draft version 1 released to CRF final version 1

Versions after initial release	Reason for change	Note
Version 2 Release date: 21-02-2013	Removed (3), (4), (5), (6), (7), (8), (9), (10), and (11)	Version 1 disabled

Ultrasound scan

- CRF draft version 5 released to CRF final version 1

Versions after initial release	Reason for change	Note
Version 2 Release date: 07-06-2012	Not applicable	Due to a misunderstanding, a new version was created, even though no changes were made.
Version 3 Release date: 07-11-2012	Added an option to tick off in a box when Ultrasound scan image is considered normal for some measure fields in the form	This addition is to ease the task of completing the form. Version 2 of the form is not to be used anymore for new Ultrasound events.
Version 4 Release date: 15-02-2013	Changed the response set for (6) to 1=yes, 0=no	Response set was incorrect.

Version 5 Release date: 21-02-2013	Split both (30) and (32) into two: (30A) and (32A) now refer to side of infarction; (30B) and (32B) refer to location of infarction.	Previous versions required two values in (30) and (32) if infarction was present, which these fields would not accept.
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aEEG / EEG Recording

- CRF draft version 1 released to CRF final version 1

MRI

- CRF draft version 2 released to CRF final version 1

Follow up - term date

- CRF draft version 4 released to CRF final version 1

Adverse events not serious

- CRF draft version 4 released to CRF final version 1

Serious Adverse Events

- CRF draft version 2 released to CRF final version 1

End of Study

- CRF draft version 1 released to CRF final version 1