Data report template on Research Ethics Boards (REBs) decision in relation to alternative consent methods in SFB-III

Dear investigator

Thank you for participating in this ancillary study of the SafeBoosC III trial. Below you will find a template for data entry. In order to qualify for co-authorship on the two planned publications, please report your data to mathias.safeboosc@gmail.com as soon as you have gotten ethics approval.

As for data regarding 'concerns or complaints in relation to the consent procedure raised by clinical staff or parents' (page 2), please report these data when your department have been enrolling babies for six months.

Data entry

Date of protocol submission to REB: _____

Date of final decision by REB: _____

What consent method did your NICU apply to use? (mark with an X)
Prior informed consent____ *Deferred consent___* *'Opt-out'____*

Did the REB raise any queries regarding this consent method? (mark with an X)
Yes____ *No_____*

If the REB raised any queries towards the consent procedure, please specify:

Did the REB grant final approval for this consent method? (mark with an X)
Yes____ *No_____*

What consent method did you end up using in the trial? (mark with an X)
Prior informed consent____ *Deferred consent___* *'Opt-out'____*

Concerns or complaints in relation to the consent procedure raised by clinical staff or parents

Please report all concerns or complaints separately.

Concern/complain 1

Who raised the concern/complaint (family or staff member)?
Please also type the relation (father, mom, grandparent etc) or clinical position (nurse, resident, consultant etc).

What was the concern/complain about?
Give a brief description

Was trial practice modified following the concern/complain and how?
Give a brief description

Concern/complain 2

Who raised the concern/complaint (family or staff member)?
Please also type the relation (father, mom, grandparent etc) or clinical position (nurse, resident, consultant etc).

What was the concern/complain about?
Give a brief description

Was trial practice modified following the concern/complain and how?
Give a brief description

Concern/complain 3

Who raised the concern/complaint (family or staff member)?
Please also type the relation (father, mom, grandparent etc) or clinical position (nurse, resident, consultant etc).

What was the concern/complain about?
Give a brief description

Was trial practice modified following the concern/complain and how?
Give a brief description