SOP: deletion of data in situations with missing or withdrawal of consent

Version	Author(s)	Date	Changes	Approved by
1.0	Mathias Lühr Hansen	26-02-2020	Initial version	Gorm Greisen

Content

1.0 Purpose of the SOP

The purpose of this Standard Operation Procedure is to outline when and how personal data should be deleted, if requested by parents.

2.0 When should data be deleted?

In SafeBoosC III, participating hospitals can apply to their Research Ethics Board to use three different consent methods; prior informed consent, 'opt-out' (prior assent) and deferred consent. When using prior informed consent or 'opt-out, consent or assent is sought from the parents before their baby is enrolled in the trial. When using deferred consent, eligible babies are enrolled immediately after birth and consent is sought later, when the emergency situation has settled.

Parents can withdraw their consent at any time and thereby, stop their baby's participation in the trial, including any future personal data collection. However, due to GDPR article 17, part 3, litra d, we are still allowed to store and use personal data up until the day of withdrawal.

In situations where deferred consent is used and the baby is randomised before consent is given by the parents, some pre-consent data collection will happen (at minimum, the data entries needed to randomise). If the parents decline participation when consent is sought after randomisation (deferred consent), they are in their right to require that all previous personal data is deleted from the trial database.

3.0 Step-by-step procedure for deletion of data entries

1) If the parents withdraw consent/decline participation after randomisation, this must be registered by the principle investigator in the 'End of monitoring (72 hours of age)' form in OpenClinica, in data point E12. The reason for withdrawal must be stated in data point E12a.
2) The principal investigator should ask the parents for permission to use data from their baby's future clinical course. The parent's decision must be registered in data point E12b.
    a. In situations with deferred consent, parents should also be asked for permission to use already registered data entries as well
3) If the parents give permission to use data from their baby's future clinical course, there will be no additional changes since data collection will continue, despite withdrawal from the trial.
4) If the parents do not give permission to use data from their baby's future clinical course, the principal investigator is responsible for contacting the Trial Manager Mathias Lühr Hansen at

mathias.luehr.hansen@regionh.dk. He will need to know the study-ID of the baby and ensure that the relevant data entry forms will be deleted accordingly.

   a. If the parents withdraw consent before end of monitoring (72 hours of age), the 'End of Monitoring (72 hours of age)' and 'Follow-up (36 weeks PMA or discharge to home)' form will be deleted. Only the Randomisation form and data entries to E12, E12a and E12b in 'the End of Monitoring (72 hours of age)' form will be saved.
   b. If the parents withdraw consent after end of monitoring (72 hours of age), but before 36 weeks of postmenstrual age, only the 'Follow-up (36 weeks PMA or discharge to home)' form will be deleted.
   c. If the parents withdraw consent after 36 weeks of postmenstrual age, no data forms will be deleted.

5) In situations where deferred consent is used and the parents do not give permission to use already registered data, the following will happen:
   a. The 'Randomisation' form will be anonymised, meaning that only participant ID, Site ID, time of randomisation, group allocation and gestational age above or below 26 weeks will be kept. All other data points will be deleted.
   b. Since we randomise and analyse by the intention-to-treat principle, the baby will still count in the sample size of 1600, but will contribute to the results by missing data, only.