SOP: Deletion of data due to withdrawal of consent or declined participation

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Purpose of the Standard Operating Procedure

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

When should data be deleted?

In SafeBoosC-IIIv, participating sites can apply to their Research Ethics Board to use three different consent methods: prior informed consent, opt-out (prior assent), and deferred informed consent. When using prior informed consent or opt-out, consent or assent is sought from the parents before their neonate is enrolled in the trial. When using deferred informed consent, eligible neonates are enrolled immediately after intubation and initiation of mechanical ventilation and consent is sought later, when the emergency situation has settled.

In situations where prior informed consent or opt-out (prior assent) is used, parents can withdraw their consent or decide to opt-out at any time and thereby stop their neonate's participation in the trial, including any future personal data collection. However, due to GDPR article 17, part 3, litra d, we are allowed to store and use personal data up until the day of withdrawal or 'opt-out'.

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

Step-by-step procedure for deletion of data entries

Neonates randomised by prior consent or assent (opt-out)

1) If the parents withdraw consent or decide to opt-out after randomisation, this must be registered by the principal investigator in the 'End of monitoring' form in OpenClinica in data point E18 (withdrawal)/E19 (opt-out). The parents should be asked for withdrawal reason/reason for opt-out, and the reason must be stated in data point E18a (withdrawal)/E19a (opt-out).
2) The principal investigator must ask the parents for permission to use data from their neonate's future clinical course. The parents' decision must be registered in data point E18b (prior consent)/E19b (opt out).
3) If the parents give permission to use data from the neonate's future clinical course, there will be no additional changes since data collection will continue, despite withdrawal or opt-out from the trial.
4) If the parents do not give permission to use data from their neonate's future clinical course, the principal investigator is responsible for contacting Johanne Juul Petersen at

johanne.juul.petersen@ctu.dk. She will need to know the study-ID of the neonate and ensure that the relevant data entry forms will be deleted accordingly.

   a. If the parents withdraw consent or opt-out before end of monitoring, any data entries in 'End of monitoring' and '90 days follow-up' forms will be deleted. Only the 'Randomisation' form and data entries to E18/E19, E18a/E19a and E18b/E19b in the 'End of monitoring' form will be saved.
   b. If the parents withdraw consent or opt-out after end of monitoring, but before day 90 after randomisation, only the '90 days follow-up' form will be deleted.
   c. If the parents withdraw consent or opt-out after 90 days after randomisation, no data forms will be deleted.

Neonates randomised by deferred consent

1) If the parents decline participation after randomisation, this must be registered by the principal investigator in the 'End of monitoring' form in OpenClinica in data point E20. The parents should be asked for the reason for declining further participation, and the reason must be stated in data point E20a.
2) The principal investigator should ask the parents for permission to use data from their neonate's future clinical course and for permission to keep and use already registered data. The parents' decision must be registered in data point E20b and E20c.
3) If the parents give permission to use data from their neonate's future clinical course and to keep and use already registered data, there will be no additional changes since data collection will continue, despite declining further participation in the trial.
4) If the parents do not give permission to use data from their neonate's future clinical course but do allow that we keep and use already registered data, the principal investigator is responsible for contacting Johanne Juul Petersen at johanne.juul.petersen@ctu.dk. She will need to know the study-ID of the neonate and ensure that the relevant data entry forms will be deleted accordingly.
   a. If the parents declined further participation before end of monitoring, any data entries in the 'End of monitoring' and '90 days follow-up' forms will be deleted. Only the 'Randomisation' form and data entries to E20, E20a, E20b and E20c in the 'End of monitoring' form will be saved.
   b. If the parents declined further participation after end of monitoring, but before day 90 after randomisation, only the '90 days follow-up' form will be deleted.
   c. If the parents declined further participation after 90 days after randomisation, no data will be deleted.
5) If 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, gestational age above or below 34 weeks, and whether mechanical ventilation was initiated due to surgery will be kept. All other data points will be deleted.
b. Since we randomise and analyse by the intention-to-treat principle, the neonate will still count in the sample size of 1610, but will contribute to the results by missing data only. In such a case, remaining data forms for the neonate will be closed and shown in red.

