

Case Report Forms

Overview of data collection forms:

Form	Format	When to complete
Enrolment form	Enrolment website (data automatically copied to OpenClinica)	When eligibility has been confirmed
Contact details form	Enrolment website	As soon as possible after enrolment
Daily dosing log	Paper copy, then transcribed to OpenClinica	From birth until baby is discharged or reaches 40 weeks postmenstrual age (whichever is sooner)
Transfer/discharge form	OpenClinica	Baby is transferred to another hospital, discharged home, reaches 40 weeks postmenstrual age, or dies
Withdrawal form	OpenClinica	Parent withdraws any time between enrolment and end of the study

NNRD data

BASE Observational Study also uses data from the [National Neonatal Research Database \(NNRD\)](#). NNRD uses data that is submitted on electronic patient record systems e.g. Badgernet. **Please ensure this data is complete and accurate as possible.**

OpenClinica access

Electronic CRFs are completed on OpenClinica. Each site staff member requires an individual account. Please contact the BASE study team if you require an account (base@npeu.ox.ac.uk)

Enrolment Website access

Enrolment is through the Enrolment Website. Each site staff member requires an individual account. Please contact the BASE study team if you require an account (base@npeu.ox.ac.uk)

Please see **Guidance Sheet: Enrolment** for more details about the Enrolment process

Enrolment and Contact details

Please see [Guidance sheet: Enrolment](#) for details of how to access the enrolment and contact details forms. The only information collected on the contact details form is the baby's postcode and (if available) their Badger ID.

The data entered at enrolment on the Enrolment website is automatically copied into an Enrolment Form on OpenClinica. If any data entered at Enrolment was incorrect, it should be amended here.

After enrolment, there is no further baseline data to enter; begin completing the Daily Dosing Log.

Daily Dosing Log

This log must be completed from birth until the baby is discharged or reaches 40 weeks postmenstrual age. A paper copy should be kept by the cot side for completion. Once completed the research nurse (or delegate) will be responsible for checking the accuracy of the data and entering into OpenClinica. The paper copy should be scanned and saved in your eISF.

Completing the log

Enter the baby's details at the top and fill in the log each day after Enrolment. Complete Table 1 each day, and complete Tables 2-3 when applicable.

Table 1 - records whether a baby meets the criteria for metabolic acidosis and if they received sodium bicarbonate that day.

Table 2 – records details of metabolic acidosis episode

Table 3 – records details of sodium bicarbonate infusion

Transfer/discharge form

Complete a transfer/discharge form for the following events:

- Transferred to another hospital
- Discharged home
- Reaches 40 weeks postmenstrual age
- Dies while in hospital

Some babies will have multiple transfer/discharge forms completed

If a baby is discharged home from, transferred from, or dies at a continuing care site, the recruiting site is responsible for completing the Transfer/Discharge Form(s) on OpenClinica. The continuing care site should send over completed paper/scanned copy.

Withdrawal Form

Please refer to [Guidance Sheet: Withdrawals](#).