

The baby being transferred to your hospital is enrolled in the **BASE observational study**. *Please note, this is different to the BASE trial.*

The BASE observational study collects data on **metabolic acidosis** in very preterm babies and **how it is managed** in clinical practice. For more information, please visit the website: <https://www.npeu.ox.ac.uk/BASE>

Participation in the study does not affect the care they receive; it is a **data-collection-only** study.

This sheet provides guidance on the steps to follow if a baby enrolled in the study is transferred to your hospital.

Please follow this guidance until the baby is discharged home or reaches 40 weeks postmenstrual age (whichever is sooner):

1. Complete the Daily Dosing log
2. If required, complete 'Additional Case Report Forms' – listed below
3. Inform the recruiting site when baby is discharged home, transferred or dies.
Complete transfer/discharge form.
4. Securely return all completed forms to the recruiting site via secure email

Please ensure your site is an **approved** Continuing Care site before carrying out any study related activities. Approved CC sites are listed on our website: www.npeu.ox.ac.uk/base If you are unsure or are not approved, please contact the BASE study team (base@npeu.ox.ac.uk).

The Transfer Pack

A transfer pack should arrive with the baby.

The contents of the Transfer Pack are:

- Photocopy of existing dosing log and additional blank copies
- BASE Parent Information Leaflet (will contain recruiting site research team contact information)
- BASE Incident Form
- BASE Transfer/Discharge Form
- BASE Guidance Sheets: Continuing Care Sites, Case Report Forms, Incident Reporting and Withdrawals
- Envelope with recruiting site's address on

NNRD data

BASE 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.**

Completion of Daily Dosing Log

When to fill in the log?

The Dosing Log must be completed for each day that the baby is an inpatient in your neonatal unit. Whenever the baby has a blood gas measurement satisfying the criteria of **blood pH <7.25 with pCO₂ that is low or normal for the clinical context and a low bicarbonate level**, and whenever the baby is given **sodium bicarbonate**, this should be recorded on the Dosing Log.

A photocopy of the current log from the Recruiting Site is included in your Transfer Pack, along with blank copies should you need them. More guidance on how to complete the Dosing Log is provided in [Guidance Sheet: Case Report Forms](#) (included in your transfer pack).

How long to collect data for?

Until the baby is discharged from neonatal care, transferred to another hospital or they have reached 40 weeks postmenstrual age (whichever is sooner).

What to do when data collection is finished?

Once completed, the Recruiting Site is responsible for entering the data on the OpenClinica database. Please send a scanned copy of the Dosing Log to the Recruiting Site by email from a secure email account.

Additional Case Report Forms

Transfer/Discharge Form

Please complete this form in the following events:

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

If a baby is due to be transferred to another hospital, please immediately notify the Recruiting Site (contact details can be found on the back of the Parent Information Leaflet).

Once a transfer has occurred, please complete the paper Transfer/Discharge Form and securely email a scanned copy to the Recruiting Site.

Incident Reporting Form

Deviations from protocol, trial specific procedures or Good Clinical Practice (GCP) must be reported to the BASE study team, using the Incident and Deviation form. A scanned copy should be sent to base@npeu.ox.ac.uk.

For guidance on how to report incidents, please refer to [Guidance Sheet: Incident Reporting](#).

Withdrawal Form

If a parent withdraws their baby from the study, please let the Recruiting Site know. They will need to complete a withdrawal form. Data collected up until the point of withdrawal will be used in the study. For more information, please refer to [Guidance Sheet: Withdrawals](#).

If you have any queries, please contact the BASE study team:

Any queries should be directed to the BASE study team during office hours (i.e. between 09:00-17:00, Monday to Friday) on 01865 289716 or email base@npeu.ox.ac.uk

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