FAQs for Recruiting Sites

During the study

1. Will staff need to be on the delegation log in order to enter data?

Yes, anyone who is entering data for the study will need to be on the delegation log.

2. How much data entry will there be?

Most of the data we need for the trial will be obtained from the National Neonatal Research Database (NNRD), which draws on data from electronic patient records (e.g., Badgernet).

Following entry on the randomisation website, site staff will also be asked to complete the following CRFs on OpenClinica:

- Entry forms
- Daily dosing log for all babies
- Transfer/discharge form

The parents/carers will also be sent a questionnaire when their baby is 24 months corrected age. The BASE study team will be responsible for contacting parents and sending out the questionnaires.

3. Do we need to maintain a dosing log for all infants regardless of which arm they are randomised to?

Yes, the dosing log should be completed daily for all infants in the study, even if they are in the no routine use of sodium bicarbonate arm. This is so we can monitor adherence to the trial arm.

4. An infant allocated to the *no routine use of sodium bicarbonate* receives sodium bicarbonate, what shall we do?

Please record this on the infant's daily dosing log. The infant will remain in the study. Note that there are some allowed uses of sodium bicarbonate, which are stated within the protocol.

5. How do we report incidents and Serious Adverse Events (SAEs)?

Please refer to the Guidance Sheet: Safety and Incident Reporting

6. What are the procedures around hospital transfer?

Please refer to the Transfer of Infants Guidance Sheet for further details. Please notify the BASE study team of any planned or completed transfers as soon as possible.

7. What is a continuing care site?

A Continuing Care Site (CCS) is a site which an infant is being transferred to from a BASE recruiting site, which is also participating in the study. CCSs cannot recruit new infants to the trial, but if the infant has already been randomised, they will be responsible for continuing treatment in line with the allocated trial arm.

CCSs will need to be set up and approved before study related activities can take place at their site. The study team will contact the R&D department to obtain these approvals. Once approved, the infant can continue following their allocated trial arm at the CCS. Note that a delegation log will not be required for continuing care sites.

CCSs should complete a paper copy of the dosing log to collect trial data. Once the baby is discharged, the CCS will send a copy of this to the recruiting site (preferably via email) to be entered onto OpenClinica. The recruiting site will be responsible for all data entry.

8. Will continuing care sites be set up routinely?

The trial team will aim to set up and approve potential continuing care sites during the site set-up process for recruiting sites. However, it can take some time to obtain approvals. Please let us know if there is a site which you frequently transfer infants to or if you are aware that an infant is going to be transferred to a particular site, so we can start the approval process as early as possible.