Guidance Sheet 4: Completion of Case Report Forms

- All case report forms are kept in the Baby-OSCAR Documentation Box. If you are running low on stock you can request more by using the Documents Request Form. Electronic copies of all case report forms are kept on the Baby-OSCAR website (https://www.npeu.ox.ac.uk/baby-oscar) and can be downloaded and printed off.

- If you make a mistake when completing a form, strike through once and initial and date the correction; please do not use Tipp-ex or scribble out the mistake.
  - If a form becomes full of mistakes please check that it is decipherable to others before sending to the Trial Co-ordinating Centre. If the form looks difficult to understand please complete a fresh form, transcribing the data carefully, checking data entered with the baby’s clinical notes.

- When a case report form is completed, please send to the Trial Co-ordinating Centre using a Freepost envelope provided in the Baby-OSCAR Documentation Box.

- Forms that are completed over a period of time (i.e. Form 2) or that are not sent to the Trial Co-ordinating Centre straightaway, should be stored in the ‘Working Documents’ section of the Baby-OSCAR Documentation Box until they are ready to be posted to the Trial Co-ordinating Centre.

- There are 5 case report forms, plus a consent form that should be completed for all babies in the trial, they are:
  - Consent Form
  - Form 1: Trial Entry
  - Form 2: Trial Medication
  - Form 3: ECHO results around 3 weeks of age
  - Form 4: 36 Week Form
  - Form 6: Baby Outcomes (Transfer, Discharge, Death)

- There are a further 5 case report forms in the Documentation Box that may be required for some babies:
  - Form 5: Open-label Treatment of PDA
  - Form 6a: Necrotising Enterocolitis Report Form
  - Form 7: Baby withdrawal Form
  - Form 8: Serious Adverse Event Report Form (SAE)
  - Form 9: Incident/deviation Report Form

- For all forms (Form 1: Trial Entry in particular), please add as much information about the baby as possible. This is particularly important if the baby has no first name yet, or it is a multiple birth e.g. Female or Male, Twin 1, Triplet 2 etc.

- All the data requested in the forms are routine clinical items that can be obtained from the clinical notes.
CHI Number: This is used in Scotland and is the NHS Scotland’s patient identification system.

Specific points to remember about each case report form

Consent Form
- This is an NCR (carbon copy) form which comprises of 4 sheets - please ensure that any signatures/initials transfer through to the subsequent duplicate sheets
- The sheets are colour coded, the top sheet should be returned to the Trial Co-ordinating Centre. Other copies are to go (i) into Data Collection File, (ii) to the parent, (iii) in the baby’s clinical notes
- When filing the copy of the Consent Form for the Data Collection File remember to also complete the Trial Participant Log in the front of the Baby-OSCAR Data Collection File
- If the father consents for the baby to participate into the trial, ensure the mother countersigns in the space provided
  o we need her consent for some of the maternal data collected at trial entry/randomisation.

Form 1: Trial Entry
- The decision for eligibility and trial enrolment must be made by a medically qualified doctor and there should be clear documentation of this in the baby’s notes
- Complete Part A of the form prior to randomisation and then transfer the data from Part A into the randomisation program
- Immediately after randomisation directly record the allocated Study Number and Pack ID Number given by the randomisation program in Part B of the form
- Complete the rest of the form and post to the Trial Office within 7 days of birth
- Do not state people’s names, other than the mother and baby’s. This is particular to question E6, where it asks for contact details, but requests relationships to be specified rather than naming people
- Section C, question C2 regarding COX inhibitors - The use of Cox inhibitor after 20 weeks’ gestation should be captured, we do not require any further details e.g. duration of cox-inhibitor/ no. of doses.
Form 2: Trial Medication Form

- Complete the form 7 days after the baby has completed trial medication, or if the baby never receives the trial medication for any reason
- If the baby is transferred within 3 days of birth please contact the Co-ordinating Centre
- Question C1, Anaemia requiring blood transfusion – you can record up to three. If a baby receives more transfusions, record on the back page
- C2, Culture proven sepsis – please record a blood/CSF culture proven sepsis ONLY. We do not require multiple samples, or intend to include ET tip/long line/UAC/UVC positive sepsis. Record the results of the first culture proven sepsis
- C6, Cerebral US – we are interested in any scan performed in the first week of life, as most scans will take place during this period. If multiple scans conducted in the first week, please record the results of the last head scan
  - In addition, ensure that you have confirmed the ‘abnormality’ or responded ‘none seen’, and ticked at least one box in both ‘left’ and ‘right’ columns.

Form 3: ECHO results around 3 weeks of age
To be completed around 3 weeks of age, or last ECHO after completing trial medication, prior to transfer, or death, or discharge if earlier
Scans should ideally be around 3 weeks (range 18 - 24 days)
- If a baby dies before day 18, and an ECHO was not carried out around this time, we would not expect to receive this form.

Form 4: 36 Week Form
To be completed at 36 weeks of PMA or at discharge if discharged home earlier. If a baby is discharged home, please ensure that a Form 6: Baby Outcomes is completed.

Only perform the oxygen reduction test if baby has received oxygen, and/or respiratory support for ≥ 28 days and the following:

- the baby is not receiving mechanical ventilation (invasive and non-invasive), CPAP, or high flow oxygen therapy
- FiO₂ < 0.3, or low flow oxygen < 1.1 L/min to maintain saturations of ≥ 91%
- In previous 24 hours, baby has not required respiratory support.

- When reporting cerebral ultrasounds (Section E), if there are multiple scans, enter the data for the scan closest to 36 weeks of postmenstrual age
  - In addition, ensure that you have confirmed the ‘abnormality’ or responded ‘none seen’, and ticked at least one box in both ‘left’ and ‘right’ columns.
Form 5: Open-label Treatment of a PDA

- Open-label treatment (both medical and surgical) is permitted within the protocol. See the front page of Form 5 for minimum criteria.
- Surgical treatment however should only be considered if the PDA remains persistently large after one course of treatment with a COX inhibitor or in circumstances where medical treatment may be contraindicated or time does not permit medical open-label treatment first.

Form 6: Baby Outcomes (Baby Transfer, Discharge or Death)

Information to be recorded on the Discharge Form should only be for the time they spent in your unit. The completed Discharge Form can be sent back to the Co-ordinating Centre in the Freepost envelope provided.

- To be completed when the baby leaves your hospital either to be transferred to another hospital or discharged home, or at death
- In the event of death please send a copy of the discharge summary and, if and when available, a copy of the post-mortem examination report
- Cerebral US – we are interested in the last scan performed at your hospital
  - In addition, ensure that you have answered ‘at least one row’, and ticked at least one box in both ‘left’ and ‘right’ columns.
- If a baby is transferred for less than 24 hours, e.g. for surgery and returned to you, there is no need to complete a separate ‘Form 6’ for this brief stay, instead incorporate the associated data on the one form; You will need to inform the surgical centre of the transfer so that you can collect any relevant data easily.

When confirming the outcome at your centre, please tick one box only, as a baby can only have one outcome e.g. they were discharged home, or transferred on for on-going care, or died.

Section F: Contact details

For contact details of other family members or others, please do not record their names, we just require their address, contact numbers and relationship to the baby.
Form 6a: NEC Form
This form must be completed along with Form 6: Baby Outcomes for all instances where the baby:

- has definitive Bell stage II or III NEC
- has been transferred with NEC
- died from NEC

If multiple episodes, complete a form for each episode.

Form 7: Baby withdrawal
- To be completed and signed by the Principal Investigator or delegated deputy for any baby who is totally withdrawn from the trial, or whose parents request to stop their baby’s ongoing participation in the trial
- It is important that you clarify with the parent(s) and record on the form whether, despite stopping the medication, they would agree to retention and use of the data already collected, for data collection to continue to completion and for any outstanding ECHOs/oxygen reduction test to be conducted
- Depending on the wishes of the parent(s) further data collection and form completion may be required
- Remember to place a copy of the completed Form in the baby’s clinical notes.

Form 8: Serious Adverse Events (SAE)
Safety reporting for the baby, as described in Section 9 of the protocol, will be monitored from first dose until 7 days after trial medication. Unforeseeable Serious Adverse Events will be reported to the NPEU CTU within 24 hours of staff at the site becoming aware of the event.

- A study physician (Investigator) is responsible for reviewing the SAE and considering whether the event was related to the study drug(s).
  - If a study physician is not available to make the causality assessment send in the SAE Reporting Form without this information and re-send the form as soon as this assessment has been made.
  - A Physician who is not a member of the study team may offer an opinion as to whether the event was related to the study drug(s) and this opinion should be documented in the participant’s medical records.

For further information, please see Guidance Sheet 6.
Form 9: Incident Reporting

Definitions

**Serious breach**
A serious breach is a breach which is likely to affect to a significant degree (a) the safety, physical or mental integrity of the participant(s) or the trial or, (b) the scientific value of the trial.

**Trial-related deviation**
A trial-related deviation is a departure from the approved trial protocol or other trial-related document or process, from the principles of GCP, or from any applicable regulatory requirements. This includes changes made to avoid immediate harm to trial participants.

- Report as soon as is practical following the incident/deviation
- Complete Form 9 and fax the completed form to the Baby-OSCAR Trial Co-ordinating Centre on 01865 289 740, or email: baby-oscar@npeu.ox.ac.uk.
- Ensure the Baby-OSCAR Trial Co-ordinating Centre is aware
- Copy the completed Form 9, send original to the Trial Co-ordinating Centre and place the copy in the baby’s clinical notes

If you are unable to record any ‘resolutions’ in the first instance – send the completed form and then re-send the form with ‘resolutions’ at a later date.