PiPS
Probiotic in Preterm babies Study

Form 3: Baby Transfer, Discharge or Death

Outcomes at this hospital

Points to remember when completing this form:

- This form should be completed at **discharge** whether to **another hospital** or to **home**, or at **death**
- If the baby is discharged to another hospital please remember to complete the **PiPS Transfer Checklist** (see Guidance Sheet 6) and inform the Trial Office of the transfer on [redacted]
- If the baby is being transferred and is below 36 weeks post-menstrual age, please also send the baby's allocated package with all the unused sachets of the intervention to the receiving hospital in the Transfer Pack
- **Only events** occurring in this hospital should be recorded on this form; a similar form will be completed in each hospital where the baby is admitted
- If the baby reached 36 weeks pma or was discharged home or died before this date while at your hospital please ensure you complete **Part C** of this form
- Until completed, keep this form in the 'Working Documents' section of the PiPS Documentation Box
- When this form has been completed, return to the Trial Office using a FREEPOST envelope from the PiPS Documentation Box **with all Form 4: Abdominal Pathology** forms which have been completed for episodes of any suspected abdominal pathology while the baby was an in-patient at your hospital
- If you make a mistake when filling out this form, strike through once and initial and date the correction (please do not use Tipp-ex!)
- Please ensure all questions on this form are answered; this will avoid unnecessary work in chasing missing data
- If you have any questions about this form or how to answer any of the questions please contact the Trial Office on [redacted]

Part A: Baby details

A1. Name of hospital: _____

A2. Study number (5 digits): | | | | | |

A3. Date of birth: D D / M M / Y Y

A4. Baby's surname: _____ **First name:** *(if known)* _____

A5. Baby's NHS number: | | | | | | | | | | |

A6. Baby's hospital number in this hospital: | | | | | | | | | | |

A7. Date of admission to this hospital*: D D / M M / Y Y

If at admission to this hospital the baby is over 36 weeks post-menstrual age you **do not need to complete **Part C** of this form.*

Part B: While in this hospital

Infections

B1. **While in this hospital were there any episodes of NEC or other abdominal pathology?** Yes ☐ No ☐

If Yes, how many episodes: 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐

*A separate Abdominal Pathology form (**Form 4**) should be completed for each episode and submitted to the PiPS Trial Office with this form.*

B2. **While in this hospital did you grow any bacteria from a normally sterile site other than blood or CSF:** *e.g. SPA, intra-operative peritoneal swab, abscess drainage etc.* Yes ☐ No ☐

If Yes, please complete table below *(blood and CSF culture data are being obtained directly from the microbiology laboratory, please don't enter here):*

Date sample taken	Sample site (e.g SPA, intra-operative swab, etc.)
D D / M M / Y Y	
D D / M M / Y Y	
D D / M M / Y Y	
D D / M M / Y Y	
D D / M M / Y Y	

Feeding

B3. **While in this hospital did the baby reach full feeds (150 ml/kg/day) for the first time?** Yes ☐ No ☐

If Yes, what was the date that the baby first reached 150 ml/kg/day of milk? D D / M M / Y Y

Note: If the baby was breast feeding before receiving 150ml/kg/day by tube please count the first day that IV fluid supplements were discontinued as the day full feeds were achieved.

(Fluid supplements should include any fluid e.g TPN or dextrose solution given as part of the baby's total fluid prescription but not fluid given solely to administer iv medications)

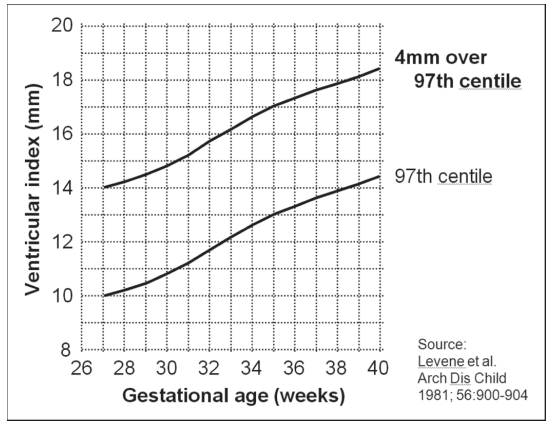
Other diagnoses

B4. While in this hospital did the baby have any cerebral ultrasound scans? Yes ☐ No ☐

If Yes, identify below any abnormalities seen on any scan in this hospital *(please tick at least one box in each column):*

Please select from the following:	Left	Right
No abnormality seen on any scan	☐	☐
Intraventricular haemorrhage (IVH)	☐	☐
Haemorrhagic parenchymal infarct (HPI)	☐	☐
Hydrocephalus (Ventricular index >4mm above 97th centile*)	☐	☐
Porencephalic cyst	☐	☐
Periventricular leucomalacia (PVL)	☐	☐

*Ventricular Index: The ventricular index is the distance between the middle and the most lateral point of the lateral ventricle in millimetres measured in the coronal (or the axial) plane at the level of the foramen Munro.



B5. While in this hospital did the baby receive treatment for Patent Ductus Arteriosus? Yes ☐ No ☐

If Yes, please indicate treatment:

Medical treatment with indometacin or ibuprofen ☐

Surgical ligation ☐

B6. While in this hospital were any congenital malformations detected? Yes ☐ No ☐

If Yes, please list congenital malformations below

B7. **While in this hospital were the eyes examined for Retinopathy of Prematurity?** Yes ☐ No ☐

If Yes, is any ROP present? Yes ☐ No ☐

If Yes, what was the worst stage of ROP in each eye?
(See stage definitions below. Please enter '0' if not present) Right Eye ☐ Left Eye ☐

Has the ROP been treated with laser or cryotherapy? Yes ☐ No ☐

If Yes: Right Eye ☐ Left Eye ☐

Definitions of stage of ROP *(Arch Opthalmol 2005;123:991-9)*:

Stage 1: Demarcation line - A thin relatively flat line separating the vascular and avascular retina. Abnormal branching or arcading of vessels may lead up to the demarcation line.

Stage 2: Ridge - The ridge has height and width extending above the retina. Isolated tufts of neovascular tissue - "popcorn" - may be seen posterior to the ridge.

Stage 3: Extraretinal Fibrovascular Proliferation - In this stage extraretinal fibrovascular proliferation or neovascularisation extends from the ridge into the vitreous.

Stage 4: Partial Retinal Detachment - Sparing macula (stage 4a) and involving macula (stage 4b).

Stage 5: Total Retinal Detachment

B8. **While in this hospital did the baby receive any antimicrobials (antibiotics or antifungals) for suspected or proven infection after 14 days post-natal age?** Yes ☐ No ☐

If Yes, please specify:

For how many days in total were antibiotics given? ☐☐☐ days

For how many days in total were antifungals given? ☐☐☐ days

(Antimicrobials used up until 14 days after birth are reported on Form 2, the Daily Data Collection form)

Please do not include days of antimicrobials given for prophylactic use e.g. prophylactic peri-operative antibiotics or prophylactic nystatin or fluconazole.

B9. **While in this hospital were any surgical procedures performed other than for duct ligation, NEC or other abdominal pathology?** Yes ☐ No ☐

If Yes, please identify procedure:

Repair of inguinal hernia ☐

Insertion of ventricular reservoir ☐

Insertion of ventriculo-peritoneal shunt ☐

Other *please specify* _____

Any abdominal surgery should be recorded separately on ***Form 4****, the Abdominal Pathology form.*

Intensive / high dependency care

See definitions on back page

B10. While in this hospital, what was the total number of days of intensive / high dependency care?

Level 1 (intensive care) ☐☐☐ days

Level 2 (high-dependency care) ☐☐☐ days

B11. While in this hospital what was the total number of days for which the baby had a central venous line (UVC, peripheral long line, Broviac etc.) ☐☐☐ days

Please do not leave date fields blank e.g. if a baby does not receive any Level 1 care please indicate as '0' days.

Trial intervention

B12. While in this hospital was the trial intervention discontinued before 36 weeks post-menstrual age for any reason other than discharge from hospital? Yes ☐ No ☐

If Yes, was the trial intervention discontinuation:

Temporary Yes ☐ No ☐

If Yes, for how many days in total was the trial intervention discontinued: ☐☐ days

Please specify reason:

Permanent Yes ☐ No ☐

If Yes, why was the trial intervention discontinued?

Please specify the date the intervention was discontinued: D D / M M / Y Y

i) Parental request Yes ☐ No ☐

*(if the baby is withdrawn at parental request please complete **Form 6** and notify the PiPS trial office as soon as possible)*

ii) Clinician recommendation Yes ☐ No ☐

Please specify reason if known:

*(if the intervention was discontinued because of an SAE please complete a **Form 5**)*

B13. While in this hospital was the baby in any other trial? Yes ☐ No ☐

If Yes, please give the trial name(s) _____

Part C: Information at 36 weeks and 0 days post-menstrual age or discharge or death if sooner

C1. While in this hospital *(Please tick one of the following options):*

i. Was the baby transferred to another hospital before 36w pma? **If Yes**, ☐ go to Part D.

ii. Did the baby reach 36 weeks pma? **If Yes**, ☐ complete the rest of Part C.

iii. Was the baby discharged home or did the baby die before 36 weeks pma? **If Yes**, ☐ complete the rest of Part C*.

**If the baby was discharged home or died before 36 weeks post-menstrual age please complete the questions below using data available as close as possible to the date of discharge or death.*

C2. What was the date the baby reached 36 weeks pma or was discharged home or died if sooner? D D / M M / Y Y

On this date:

i. Was the baby still receiving any mechanical respiratory support including nCPAP or via a humidified high flow device e.g. Vapotherm delivering ≥2l/min? Yes ☐ No ☐

ii. Had the baby been given post-natal corticosteroids at any time with the intention to reduce the severity of Bronchopulmonary Dysplasia? Yes ☐ No ☐

iii. Was the baby receiving supplementary oxygen? Yes ☐ No ☐

*If prior to **this date** the baby has been stable in air and on this date the baby goes **briefly** into oxygen for an event such as a hernia repair or ROP treatment please answer 'No'*

If Yes,

Was the oxygen <30% ☐ **or** ≥30% ☐

Or if the oxygen was given by nasal cannulae

Was the oxygen ≤0.1l/min ☐ **or** >0.1l/min ☐

C3. As close as possible to the date the baby reached 36w or was discharged home or death:

i. What was the baby's weight ☐☐☐☐ g Date of measurement D D / M M / Y Y

ii. What was the baby's OFC ☐☐.☐ cm Date of measurement D D / M M / Y Y

C4. Was a stool sample collected as close as possible to 36 weeks pma?* Yes ☐ No ☐

If Yes, when was it sent off? *(if known)* D D / M M / Y Y

**If the baby was discharged home before 36 weeks a stool sample should be collected as close as possible to discharge (see stool collection step by step guide in the Guidance Sheet booklet).*

C5. What was the last day the trial intervention was given? D D / M M / Y Y

At 36 weeks and 0 days pma or discharge home or death, if sooner, the remaining sachets should be retained in the allocated package. A 'Course Finished' label from section 20 of the PiPS Documentation Box should be applied over the broken silver security tab on the front of the package and it should be retained for a PiPS research nurse to collect (see Guidance Sheet 4).

Part D: Baby's outcome

Baby's outcome in this hospital *(Please complete only one of the following questions - D1, D2 or D3)*

D1. Discharged home: Date of discharge D D / M M / Y Y

D2. Transferred to another hospital: Date of transfer D D / M M / Y Y

Name, address and telephone number of receiving hospital:

Name of receiving consultant *(if known)*

D3. Death: Date of death D D / M M / Y Y

i. Is a post-mortem examination planned or already performed? Yes ☐ No ☐

ii. What do you consider the principal cause of death *(Please only tick one of the following options)*

Respiratory failure	☐	Congenital malformation	☐
Brain injury	☐	Infection	☐
NEC	☐	Other gut pathology	☐

Other please specify

iii. Was intensive care actively withdrawn? Yes ☐ No ☐

If the baby died, please send a copy of the discharge summary and, if available, the post-mortem report to the PiPS Trial Office.

Part E: Contact details *Please provide as much detail as possible*

Mother:

First Name:
Surname:
Address:
Telephone:
Mobile:
Email:

Father:

First Name:
Surname:
Address:
Telephone:
Mobile:
Email:

Family Doctor:

First Name:
Surname:
Address:
Telephone:
Email:

Paediatrician responsible for follow up:

First Name:
Surname:
Address:
Telephone:
Email:

Part F: Details of the person completing this form

F1. **Date this form was completed** D D / M M / Y Y

F2. **Name of person completing this form**

Name *(Print)*: _____ Signature: _____

F3. **What is the best way of contacting you?**

When this form is complete

When this form is complete return with all Abdominal Pathology Forms (Form 4) which have been completed for episodes of any suspected abdominal pathology while the baby was an in-patient at your hospital to the Trial Office using a FREEPOST envelope from the PiPS Documentation Box

Definitions for intensive / high dependency care

Intensive care includes babies:

Receiving any respiratory support via an endotracheal tube and in the first 24 hours after its withdrawal

Receiving nCPAP for any part of the day and less than five days old

Below 1000g current weight and receiving nCPAP for any part of the day and for 24 hours after withdrawal

Less than 29 weeks' gestational age and less than 48 hours old

Requiring major emergency surgery, for the pre-operative period and post-operatively for 24 hours

Requiring complex clinical procedures:

- Full exchange transfusion
- Peritoneal dialysis
- Infusion of an inotrope, pulmonary vasodilator or prostaglandin and for 24 hours afterwards

Any other very unstable baby considered by the nurse-in-charge to need 1:1 nursing

A baby on the day of death

High dependency cares includes babies:

Receiving nCPAP for any part of the day and not fulfilling any of the criteria for intensive care

Below 1000g current weight and not fulfilling any of the criteria for intensive care

Requiring parenteral nutrition

Having convulsions

Receiving oxygen therapy and below 1500g current weight

Requiring treatment for neonatal abstinence syndrome

Requiring specified procedures that do not fulfil any criteria for intensive care:

- Care of an intra-arterial catheter or chest drain
- Partial exchange transfusion
- Tracheostomy care until supervised by the parent

Requiring frequent stimulation for severe apnoea