PiPS
Probiotic in Preterm babies Study

# Form 1: Trial Entry

Please complete in black ballpoint pen

## The eligibility (inclusion) criteria for PiPS are:

- Gestational age between or equal to **23 weeks and 0 days** and **30 weeks and 6 days** by the best assessment **and**
- Less than **48 hours** old **and**
- Parental written informed consent obtained

## The exclusion criteria for PiPS are:

- A lethal congenital abnormality known at trial entry* **or**
- Any known gastro-intestinal malformation* **or**
- No realistic chance of survival

* Any baby discovered later to have a potentially lethal or a gastro-intestinal malformation may remain in the trial, at the discretion of parents and clinicians

Babies receiving antibiotics from birth for suspected or proven infection are eligible for the trial.

**Points to remember when completing this form:**

- Until complete keep this form in the 'Working Documents' section of the PiPS Documentation Box
- This Form must be completed **within 7 days** of birth and returned to the Trial Office using a FREEPOST envelope from the PiPS Documentation Box
- **Please remember** to complete the '**Trial Participant Log**' in the PiPS Data Collection file and apply the '**PiPS Intervention Schedule**' label to the allocated package noting when the last dose should be given.
- 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: Eligibility

**A1. What was the expected date of delivery (EDD)?**
*(best estimate, derived from first ultrasound dating scan if possible)* D D / M M / Y Y

**A2. What was the actual date and time of birth?** D D / M M / Y Y h h : m m (24hr)

**A3. What is the baby's sex?** Male ☐ Female ☐ Indeterminate ☐

**A4. Is the baby a singleton or multiple birth?** Singleton ☐ Multiple ☐

**A5. Do you have written parental consent for the baby's participation?** Yes ☐ No ☐

**A6. Name of person completing Part A of the form:**

Name *(Print)*: _____ Signature: _____

## Part B: Randomisation

At randomisation you will be given the baby's 5 digit 'Study Number' and a 'Package ID Number' for the package of trial intervention allocated for this baby; this number will have 4 digits preceded by a letter. **The package should be available on the Neonatal Unit.**

**B1. Study number (5 digits):** ☐☐☐☐☐

**B2. Trial intervention Package ID Number (1 letter + 4 digits):** ☐☐☐☐☐

**As soon** as you have identified the correct package you should **immediately** write the baby's

i. Name
ii. Date of Birth
iii. Study Number

on the outside of the package in the space provided and apply the '**PiPS Intervention Schedule**' label attached to this page to the front of the allocated package below the silver security tab (see Guidance Sheet 2) noting when the last dose should be given using the information from the randomisation printout. **Then prescribe** the intervention on the baby's drug chart using the wording:

**'PiPS intervention nnnnn, 1ml daily, within 3hrs of preparation'**

The package ID number 'nnnnn' (1 letter + 4 digits) **must** be specified on the prescription and checked with each dose of the intervention.

Inside the package are foil sachets containing the intervention as freeze dried powder. Each sachet is identified with the same number as the package. The first dose should be given as soon as possible and directions for preparing and administering the intervention are given in Guidance Sheet 3.

**B3. Date the first dose of PiPS trial intervention was given:** D D / M M / Y Y

**B4. Time the first dose of PiPS trial intervention was given:** h h : m m (24hr)

**B5. Name of person completing Part B of the form:**

Name *(Print):* _____ Signature: _____

## Part C: Maternal and obstetric details

Please complete the remainder of this form as soon as you can and return to the PiPS Trial Office **within a week of birth**.

**C1. Was the baby born in this hospital?** Yes ☐ No ☐

**If No**, where was the baby born? _____

**C2. Mother's surname:** _____ **First name:** _____

**C3. Mother's date of birth:** D D / M M / Y Y

**C4. Mother's NHS number:** *(if known)* ☐☐☐☐☐☐☐☐☐☐

**C5. What was the mother's full postcode at the time of the baby's birth?** ☐☐☐☐ ☐☐☐

**C6. What is the mother's ethnic group?** *(please tick)*

| | | |
|---|---|---|
| White - British/Irish ☐ 1 | Mixed - White and Asian ☐ 5 | Chinese ☐ 11 |
| White - Other ☐ 2 | Mixed - Other ☐ 6 | Any other ethnic category ☐ 12 |
| Mixed - White and Black Caribbean ☐ 3 | Asian - Indian ☐ 7 | Black - Caribbean ☐ 13 |
| Mixed - White and Black African ☐ 4 | Asian - Pakistani ☐ 8 | Black - African ☐ 14 |
| | Asian - Bangladeshi ☐ 9 | Black - Other ☐ 15 |
| | Asian - Other ☐ 10 | Not known ☐ 16 |

**C7. Was the mother given any ante-natal steroid to improve lung maturation?**

- No ☐
- Yes, started less than 24h before birth ☐
- Yes, started 24 or more hours before birth ☐
- Unknown ☐

**C8. Did the membranes rupture more than 24h before birth?** Yes ☐ No ☐ Unknown ☐

**C9. Was a clinical diagnosis of chorioamnionitis made in the 24h before birth?**

Yes ☐ No ☐ Unknown ☐

**C10. Did the mother receive antibiotics in the 24h before birth?** Yes ☐ No ☐ Unknown ☐

**If Yes**, please list all antibiotics given:

i. _____

ii. _____

iii. _____

iv. _____

# Part D: Neonatal details

**D1. Baby's surname:** _____ **First name:** *(if known)* _____

**D2. Baby's NHS number:** ☐☐☐☐☐☐☐☐☐☐

**D3. Baby's hospital number in this hospital:** ☐☐☐☐☐☐☐☐☐☐

**D4. What was the baby's mode of delivery?** *(please only tick one of the following)*

- Vaginal birth – cephalic ☐
- Vaginal birth – breech ☐
- Vaginal birth – other presentation ☐
  - **If Other**, please specify _____
- Caesarean section before onset of labour ☐
- Caesarean section after onset of labour ☐

**D5. Were forceps or Ventouse used to effect delivery?** Yes ☐ No ☐

**D6. What was the main cause of the preterm birth?** *(please only tick one of the following)*

- Prelabour rupture of membranes (PPROM) ☐
- Preterm labour (without PROM) ☐
- APH ☐
- PIH (+/- APH) ☐
- Other maternal illness* ☐
- Poor fetal growth (mother well) ☐

***Other maternal illness:** Any pregnancy where the main reason for preterm delivery was a maternal problem such as infection, renal disease or pre-pregnancy diabetes, hypertension or trauma.

**D7. What was the baby's birthweight?** ☐☐☐☐ g

**D8.** **Was the baby one of a multiple pregnancy?** Yes ☐ No ☐

**If Yes**, how many babies were born? ☐

What was the birth order of this baby? ☐

**D9.** **Was the baby's heart rate >100bpm at 5 minutes of age?** Yes ☐ No ☐

**D10.** **What was the baby's temperature when first admitted to the neonatal unit?** ☐☐.☐ °C

**D11.** **What was the Apgar score at 5 minutes?** ☐☐

**D12.** **What was the baby's worst base excess in the first hour after birth?** ☐☐.☐

## Part E: Hospitals to which this baby may be transferred

We aim to continue the intervention until 36 weeks post-menstrual age and data collection until discharge. Many babies in the trial are likely to be transferred to a hospital nearer home before 36 weeks. In order to complete the intervention and data collection the PiPS trial will need to have R&D approval in that hospital. We are therefore asking you to tell us where the baby might be transferred to so we can confirm that we have the necessary authorisations and have provided training at that hospital.

**E1.** **Is this baby likely to be transferred to another hospital before discharge home?** Yes ☐ No ☐

**If Yes**, please list the names of the hospitals to which the baby is most likely to go:

i. _____

ii. _____

iii. _____

iv. _____

## 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 section of the form:**

Name *(Print)*: _____ Signature: _____

**F3.** **Name of hospital:** _____

**F4.** **What is the best way of contacting you?**

## When this form is complete

Please return to the PiPS Trial Office using a PiPS FREEPOST envelope within **7 days of birth**.

npeu National Perinatal Epidemiology Unit

Queen Mary University of London

University of Oxford