



Form 6: Intervention Discontinuation or Trial Withdrawal

Please complete in black ballpoint pen

Please complete this form in the following circumstances:

1. If the parents wish to stop the trial intervention
2. If the parents wish to stop their baby's ongoing participation in the trial after the trial intervention has completed
3. If the baby is withdrawn from the trial for any other reason*

* Recommendations by the clinical team to discontinue the trial intervention should not usually lead to withdrawal of the baby from the trial - details of the discontinuation should be entered in question **B12** on the Baby Transfer, Discharge or Death Form (Form 3). In this circumstance Form 6 does not need to be completed.

Points to remember when completing this form:

- A parent has the **right to withdraw** their baby from the trial at any time and for any reason, without prejudice to the baby's care. They are not obliged to provide a reason for their change of mind
- **Please clarify** with the parents whether, despite stopping the intervention, they would agree for data collection to continue and for any outstanding stool samples (due at 2 weeks post-natal and 36 weeks post-menstrual age) to be collected
- If the baby is withdrawn due to an adverse event, the investigator should determine whether a **Form 5** needs to be completed and arrange for follow-up until the adverse event has resolved
- **Do not forget** to cancel the prescription for the trial intervention on the baby's drug chart and record the date the intervention was permanently discontinued in question **B1** of this form
- Apply a '**Course Finished**' label from section 20 of the PiPS Documentation Box over the broken silver security tab on the front of the package and retain the package for a PiPS research nurse to collect (see Guidance Sheet 4)
- When this form has been completed **make a copy**, return the original to the Trial Office using a FREEPOST envelope from the PiPS Documentation Box and place the copy in the baby's clinical notes
- 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:

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

Part B: Details

B1. Date of discontinuation of intervention or withdrawal from trial:

 DD / MM / YY

B2. Why was the intervention discontinued, or the baby withdrawn?

(Please tick one of the following)

Parental wish

Other

Please list any further information:

B3. Have the parents agreed that the data already collected can be used?

Yes No

B4. Have the parents agreed that we can continue to collect clinical data until the baby is discharged from hospital?

Yes No

B5. Have the parents agreed that we may collect any outstanding stools (due at 2 weeks post-natal and 36 weeks post-menstrual age)?

Yes No

Part C: Details of person completing form

Name of Principal Investigator or consultant or PiPS research nurse completing this form

C1. Date this form was completed:

 DD / MM / YY

C2. Name of person completing this form:

Name: *(Print)* _____ Signature: _____

C3. What is the best way of contacting you?

What to do now

Please cancel the prescription for the PiPS trial intervention on the baby's drug chart, apply a 'Course Finished' label to the broken security tab and retain the package for a PiPS research nurse to collect.

When this form is complete, please place a copy in the baby's clinical notes and return the original to the Trial Office using a FREEPOST envelope from the PiPS Documentation Box.