eCRF Paper Workbook

This workbook is to be used as an aide memoire only, it does not replace the electronic CRF (MACRO).
All paper workbooks and additional forms should be retained in the Investigator Site File as they represent Source Data.

Mother's Initials: | | | |

(If only two initials are given then please separate with a hyphen)

Infant ID: | | | | | | - | |

Sponsor: University Hospitals of Derby and Burton NHS Foundation Trust

CRF Version: Final Version 1.5

PLEASE ATTACH ANY ADDITIONAL FORMS TO THIS WORKBOOK

This includes the following forms: Late-Onset Infection, Gut Signs, Daily data collection (aide memoire) and SAEs

Mother's Initials: | | | | Infant ID: | | | | | | – | |

This workbook has been produced to assist with the data collection for the FEED1 trial.

Please ensure that data collected using this workbook is entered into the electronic CRF (MACRO) within 7 days of being collected, where possible.

The electronic CRF can be found at the below link:

https://macro02.nottingham.ac.uk/

Should any of the below additional forms be used for this infant, please attach them to this workbook.

- Daily data collection
- Gut signs
- Late-onset infection
- Serious Adverse Event (SAE) reporting form

The original copies of all CRF workbooks and additional forms must be kept in a secure location.

Should you have any queries regarding the data collection process, please contact the trial coordinating centre:

Email: feed1@nottingham.ac.uk

Telephone: 0115 82 31592

Mother's Initials: ☐☐☐ Infant ID: ☐☐☐☐☐☐–☐

Neonatal	
Was this infant delivered via caesarean section?	Yes ☐ No ☐
Were the membranes ruptured >24 hours before delivery?	Yes ☐ No ☐
Was this infant's heart rate >100 bpm at 5 minutes of age?	Yes ☐ No ☐
What was this infant's temperature when first admitted to the first neonatal unit? (°C)	☐☐.☐
What was this infant's worst base excess measured within 24 hours of birth?	***Please indicate if this was a positive or negative value*** ☐☐.☐ Positive ☐ Negative ☐
Was this infant receiving respiratory support at the time of randomisation?	Yes ☐ No ☐
If yes, select support (Tick all that apply)	Mechanical ventilation ☐ CPAP ☐ Heated humidified flow nasal cannula therapy ☐ Any other supplemental oxygen ☐

Mother's Initials: ☐☐☐ Infant ID: ☐☐☐☐☐☐–☐

Daily feed log (day 1-7)							
Feeding allocation *(as per randomisation)*	Full milk feed ☐ Gradual milk feed ☐						
Day	**1**	**2**	**3**	**4**	**5**	**6**	**7**
Date (dd-mmm-yyyy)	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy
Complete the weight (in g) used to calculate the volume of fluids/feeds given today							
Weight (g) used to calculate the volume of fluids/feeds given?							
Enteral Feeds							
Total milk feed volume received per day (ml)							
Complete the volume (in ml) of each type of milk per day *(enter 0 if no milk given)*							
Expressed Mother's breast milk							
Human donor milk							
Preterm formula milk							
Term formula milk							
Was breast milk fortifier added to any breast milk today	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Was the baby breast fed today?	Yes* ☐ No ☐	Yes* ☐ No ☐	Yes* ☐ No ☐	Yes* ☐ No ☐	Yes* ☐ No ☐	Yes* ☐ No ☐	Yes* ☐ No ☐
*For breast fed babies, where milk volume is unknown, is the baby considered fully fed today by combination of breast/milk feeding?	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Did the infant receive IV fluids on this day?	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Did the infant received parenteral nutrition on this day	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
How many hours of IV fluids and/or parenteral nutrition did the infant have on this day? (Excluding any fluid infusion used for maintaining venous line patency or infusions via arterial lines)							

Continued overleaf

Mother's Initials: ☐☐☐ Infant ID: ☐☐☐☐☐☐–☐

Day	1	2	3	4	5	6	7
Antibiotic and Antifungal *(excluding prophylactic antifungal treatment)* information							
Date (dd-mmm-yyyy)	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy
Were antibiotics/ antifungals given on this day?	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Please complete a Late-Onset Invasive Infection form if 5 consecutive days are ticked (72 hours after birth) or if this infant died from suspected late-onset infection							
Were feeds stopped or withheld for more than 4 hours on this day?	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Please complete a Gut signs form if 5 consecutive days are ticked or if this infant died from suspected NEC							
Cannula Information This includes all the new intravenous cannulas that were inserted today and were used to give any Intravenous fluid or medication							
Is there an IV cannula in today?	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐
*How many new cannulas inserted today							
Central venous line Information							
Is there a central venous line in today *(including UVC/ longline/ surgical lines)?*	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐
*How many were inserted today?							
Hypoglycemia Information							
Number of times Blood glucose tested today?							
Was the Blood glucose test result(s) <2.2 mmol/L	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐
**If yes please complete a Hypoglycemia form (see page 10 of this workbook)*							

Mother's Initials: ☐☐☐ Infant ID: ☐☐☐☐☐☐–☐

Daily feed log (day 8-14)

Feeding allocation *(as per randomisation)*	Full milk feed ☐ Gradual milk feed ☐

Day	**8**	**9**	**10**	**11**	**12**	**13**	**14**
Date (dd-mmm-yyyy)	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy
Complete the weight (in g) used to calculate the volume of fluids/feeds given today							
Weight (g) used to calculate the volume of fluids/feeds given?							
Enteral Feeds							
Total milk feed volume received per day (ml)							
Complete the volume (in ml) of each type of milk per day *(enter 0 if no milk given)*							
Expressed Mother's breast milk							
Human donor milk							
Preterm formula milk							
Term formula milk							
Was breast milk fortifier added to any breast milk today	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Was the baby breast fed today?	Yes* ☐ No ☐	Yes* ☐ No ☐	Yes* ☐ No ☐	Yes* ☐ No ☐	Yes* ☐ No ☐	Yes* ☐ No ☐	Yes* ☐ No ☐
*For breast fed babies, where milk volume is unknown, is the baby considered fully fed today by combination of breast/milk feeding?	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Did the infant receive IV fluids on this day?	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Did the infant received parenteral nutrition on this day	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
How many hours of IV fluids and/or parenteral nutrition did the infant have on this day? (Excluding any fluid infusion used for maintaining venous line patency or infusions via arterial lines)							

Continued overleaf

Mother's Initials: ☐☐☐ Infant ID: ☐☐☐☐☐☐–☐

Day	8	9	10	11	12	13	14
Antibiotic and Antifungal *(excluding prophylatic antifungal treatment)* information							
Date (dd-mmm-yyyy)	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy
Were antibiotics/ antifungals given on this day?	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Please complete a Late-Onset Invasive Infection form if 5 consecutive days are ticked (72 hours after birth) or if this infant died from suspected late-onset infection							
Were feeds stopped or withheld for more than 4 hours on this day?	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Please complete a Gut signs form if 5 consecutive days are ticked or if this infant died from suspected NEC							
Cannula Information This includes all the new intravenous cannulas that were inserted today and were used to give any Intravenous fluid or medication							
Is there an IV cannula in today?	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐
*How many new cannulas inserted today							
Central venous line Information							
Is there a central venous line in today *(including UVC/ longline/ surgical lines)?*	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐
*How many were inserted today?							
Hypoglycemia Information							
Number of times Blood glucose tested today?							
Was the Blood glucose test result(s) <2.2 mmol/L	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐
**If yes please complete a Hypoglycemia form (see page 10 of this workbook)*							

Mother's Initials: ☐☐☐ Infant ID: ☐☐☐☐☐☐–☐

Daily feed log (day 15-21)							
Feeding allocation *(as per randomisation)*	Full milk feed ☐ Gradual milk feed ☐						
Day	**15**	**16**	**17**	**18**	**19**	**20**	**21**
Date (dd-mmm-yyyy)	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy
Complete the weight (in g) used to calculate the volume of fluids/feeds given today							
Weight (g) used to calculate the volume of fluids/feeds given today?							
Enteral Feeds							
Total milk feed volume received per day (ml)							
Complete the volume (in ml) of each type of milk per day *(enter 0 if no milk given)*							
Expressed Mother's breast milk							
Human donor milk							
Preterm formula milk							
Term formula milk							
Was breast milk fortifier added to any breast milk today	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Was the baby breast fed today?	Yes* ☐ No ☐	Yes* ☐ No ☐	Yes* ☐ No ☐	Yes* ☐ No ☐	Yes* ☐ No ☐	Yes* ☐ No ☐	Yes* ☐ No ☐
*For breast fed babies, where milk volume is unknown, is the baby considered fully fed today by combination of breast/milk feeding?	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Did the infant receive IV fluids on this day?	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Did the infant received parenteral nutrition on this day	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
How many hours of IV fluids and/or parenteral nutrition did the infant have on this day? (Excluding any fluid infusion used for maintaining venous line patency or infusions via arterial lines)							

Continued overleaf

Mother's Initials: ☐☐☐ Infant ID: ☐☐☐☐☐☐–☐

Day	15	16	17	18	19	20	21
Antibiotic and Antifungal *(excluding prophylatic antifungal treatment)* information							
Date (dd-mmm-yyyy)	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy	dd-mmm-yyyy
Were antibiotics/ antifungals given on this day?	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Please complete a Late-Onset Invasive Infection form if 5 consecutive days are ticked (72 hours after birth) or if this infant died from suspected late-onset infection							
Were feeds stopped or withheld for more than 4 hours on this day?	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐
Please complete a Gut signs form if 5 consecutive days are ticked or if this infant died from suspected NEC							
Cannula Information This includes all the new intravenous cannulas that were inserted today and were used to give any Intravenous fluid or medication							
Is there an IV cannula in today?	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐
*How many new cannulas inserted today							
Central venous line Information							
Is there a central venous line in today *(including UVC/ longline/ surgical lines)?*	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐
*How many were inserted today?							
Hypoglycemia Information							
Number of times Blood glucose tested today?							
Was the Blood glucose test result(s) <2.2 mmol/L	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐	Yes* ☐ no ☐
**If yes please complete a Hypoglycemia form (see page 10 of this workbook)*							

Mother's Initials: ☐☐☐ Infant ID: ☐☐☐☐☐☐–☐

Clinically Appropriate Alterations from Allocated Feeding Regime	
FEED1 feeding protocol: Full milk: infant is expected to have a total of ≤24hours IV fluids/parenteral nutrition from birth to achieving full feeds. Gradual milk: infant is expected to have a total of >24hours IV fluids/parenteral nutrition from birth to achieving full feeds.	
Did the infant's *actual* feeding regime meet the above *expected* criteria?	☐ Yes ☐ No*
*Please state the main reason for altering from the allocated feeding regime	☐ Parental choice ☐ Not tolerating feeds (e.g. vomiting, large aspirates) ☐ Hypoglacemia, needing IV glucose ☐ Escalation of respiratory support (inc. needing mechanical ventilation) ☐ Abdominal concerns, including suspected NEC ☐ Other clinical deterioration ☐ Unable to get IV access ☐ Clinical decision to stop gradual feeds and move to full milk ☐ Other clinical reasons* ☐ Other **non**-clinical reasons**
*if other clinical reasons please specify	
if other **non-clinical reasons please specify	

Hypoglycaemia details		
Please enter details for Blood glucose results <2.2 mmol/L		
Date (dd-mmm-yyyy)	**Time** (hh:mm)	**Value**

Mother's Initials: ☐☐☐ Infant ID: ☐☐☐☐☐☐–☐

Discharge Home	
Please note, this form should only be completed once for each infant, at the point in which they are transferred <u>home</u>. This form should not be completed at the time an infant is transferred to a different hospital or has passed away whilst in your hospital. For infants who have been transferred to another hospital, you should liaise with the receiving hospital and consult badgernet (or similar) to ensure that this information is entered at the time of discharge <u>home</u>.	
Date of discharge home (dd-mmm-yyyy)	☐☐ ☐☐☐ ☐☐☐☐
Weight at discharge home *(g)*	☐☐☐☐
Date infant first regained birth weight (dd-mmm-yyyy)	☐☐ ☐☐☐ ☐☐☐☐
Head circumference at discharge home *(cm)*	☐☐.☐
Was length of infant measured at discharge home?	Yes* ☐ No ☐
*Length of infant i.e. crown to heel at discharge home *(cm)*	☐☐.☐
Modes of feeding at discharge home: *(please tick all that apply)*	Breast feeding ☐ Cup feeding ☐ Bottle feeding ☐ Nasogastric tube ☐ Gastrostomy tube ☐
	Types of feeding
Types of milk for feeding at discharge home: *(please tick all that apply)*	Breast fed on demand ☐ Expressed Mothers breast milk ☐ Human donor milk ☐ Preterm formula milk ☐ Term formula milk ☐ Hydrolysed formula milk or lactose free formula milk (e.g. Enfamil, Nutramigen, Pepti junior) ☐ Amino acid-based formula milk (e.g. Neocate, PureAmino) ☐

	Term formula milk with increased energy (other than preterm formula) (e.g. SMA high energy or Infatrini)	☐
	Other*	☐
*If other, please specify		
Please specify the type of formula at discharge home	Nutriprem 1	☐
	Nutriprem 2	☐
	Neocate	☐
	Nutramigen	☐
	Pepti Junior	☐
	Infatrini	☐
	SMA High Energy	☐
	Aptamil First milk	☐
	Cow and Gate First Infant Milk	☐
	SMA First Infant Milk	☐
	Enfamil A.R.	☐
	Aptamil Preterm	☐
	SMA Gold Prem 1	☐
	SMA Gold Prem 2	☐
	Aptamil Pepti 1	☐
	Aptamil Pepti 2	☐

	Pregestimil ☐ Caprilon ☐ Wysoy ☐ Infasoy ☐ SMA Breast Milk Fortifier ☐ Cow and Gate Nutriprem Milk Fortifier ☐ Other* ☐
*If other, please specify	
Please tick if Breast milk fortifier is being used at discharge home	Breast milk fortifier ☐
Please state the number of days Parental nutrition was received in this admission	☐☐
Please state the number of days central lines were used in this admission	☐☐
Discharge Home (Continued)	
Please state the number of central venous lines inserted in this admission *(including umbilical and percutaneous or surgically inserted venous lines)*	☐☐
While in this unit during this admission, how many days did this infant receive: (HRG = Health Resource Group) *If no days were in one of the following care groups please enter 0*	
Intensive Care (HRG XA01Z)	☐☐
High Dependency Care (HRG XA02Z)	☐☐
Special Care (HRG XA03Z)	☐☐
Special Care with Primary Carer Resident or Transitional Care (HRG XA04Z)	☐☐

Mother's Initials: ☐☐☐ Infant ID: ☐☐☐☐☐☐–☐

Were any of the following diagnosed during this infant's stay in the unit?	
Retinopathy of prematurity treated medically or surgically	Yes* ☐ No ☐
*If yes,	Laser ☐ Cryotherapy ☐ Anti-VEGF Injection ☐
Bronchopulmonary dysplasia; mechanical ventilator support via endotracheal tube or nasal CPAP at 36 weeks PMA; or supplemental oxygen at 36 weeks PMA	Yes ☐ No ☐
Intracranial abnormality:	Yes* ☐ No ☐
*If yes	Grade1 IVH/Germinal Matrix Haemorrhage ☐ Grade 2 IVH ☐ Grade 3 IVH (distension) ☐ Grade 4 IVH (parenchymal involvement) ☐
Periventricular leukomalacia:	Yes ☐ No ☐
Shunt for hydrocephalus:	Yes ☐ No ☐
Late onset invasive infection	Yes* ☐ No ☐
*If yes, please ensure Late onset Invasive infection form has been completed for each episode	
Necrotising enterocolitis (Bell stage 2 or 3)	Yes* ☐ No ☐
*If yes, please ensure that a Gut Signs Form has been completed for each episode	

Mother's Initials: | | | | Infant ID: | | | | | | – | |

Discharge criteria definitions	
Weight:	**Date when infant reached ≥1700g** ***Please note, if the infant has not reached 1700g prior to discharge, it may be possible to obtain this date from BadgerNet or the home care team.***
Feeding:	**Date when infant was able to take at least one full suck feed in the last 24 hours**
Temperature control:	**Date when infant maintained body temperature without additional temperature support for at least 24 hours**
Date when all 3 of the discharge criteria as per the definitions above were first met (dd-mmm-yyyy)	| | | | | | | | | | |

Following hospital discharge please check that the following details have been added to the Randomisation database:-

- Infant's name and NHS number
- Mother's demographic questions have been completed
- Written Informed consent, if on the Oral assent pathway has been collected.

Transfer 1	
Infant Transferred to another hospital	
Name of Hospital	
Town of Hospital	
Name of receiving consultant *(if known)*	
Date of transfer (dd-mmm-yyyy)	__ __ ___ ____ ____ ____

Transfer 2	
Infant Transferred to another hospital	
Name of Hospital	
Town of Hospital	
Name of receiving consultant *(if known)*	
Date of transfer (dd-mmm-yyyy)	__ __ ___ ____ ____ ____

Transfer 3	
Infant Transferred to another hospital	
Name of Hospital	
Town of Hospital	
Name of receiving consultant *(if known)*	
Date of transfer (dd-mmm-yyyy)	__ __ ___ ____ ____ ____

Protocol Deviations
Please enter any protocol deviations directly into the electronic CRF.

Death	
Has the Infant died?	Yes ☐ No ☐
Date of death (dd-mmm-yyyy)	☐☐ ☐☐☐ ☐☐☐☐
Primary cause of Death	
Secondary cause of Death	

Cessation/discontinuation of trial activities	
*Please use the below form to report infants who have discontinued **ANY** trial related activity but who have not withdrawn (e.g. happy to provide routine data but do not wish to be contacted for 6-week follow-up):*	
Has the decision been made for the infant to discontinue from **ANY** trial activities?	Yes ☐ No ☐
*If yes, please state discontinuation type (tick any activity that the infant WILL NO LONGER participate in)	Provision of routine data ☐ 6-week Follow-up questionnaire and reminders ☐ Study results communications ☐ Contact for future studies ☐ Contact for follow-up in early childhood ☐
Date of Discontinuation (dd-mmm-yyyy)	☐☐ ☐☐☐ ☐☐☐☐
Reason for discontinuation	

Withdrawal of Infant	
*Please use the below table to report only infants who have withdrawn from **ALL** trial-related activity*	
Has the participant withdrawn from **ALL** trial-related activities?	Yes ☐ No ☐
Date of withdrawal (dd-mmm-yyyy)	☐☐ ☐☐☐ ☐☐☐☐
Reason for withdrawal	Mother withdrew infant ☐ Clinician Decision ☐ Other* ☐
*please specify	

Please note the PI will be required to login to Macro database to review and sign off each CRF once all data has been completed, the NCTU will contact site when this can be done.