Induction of labour for predicted macrosomia – 'The Big Baby Trial'

Case Report Form (CRF) Booklet

Screening Number	S								
Study Number									
Is the woman randomised or in the cohort trial?	RCT								
	Cohort								
Obstetric unit name –N.B. please do not write the name of the Trust									

Section 1 Eligibility

Visit Date ☐☐/☐☐/☐☐☐☐ Screening Number S☐☐☐☐☐☐☐☐

Study Number ☐☐☐☐☐☐☐☐

Screening – Please only complete this Case Report Form for patients who are thought to be eligible to enter the trial

Eligibility Check	
1. GROW App calculation	
Date of scan for calculation of estimated delivery date (dating scan)	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy
Estimated delivery date from dating scan	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy
Gestation at dating scan	☐☐+☐ wk+d
Woman's height at booking	☐☐☐ cm
Woman's weight at booking	☐☐☐ Kg
Parity (number of births ≥ 24 weeks)	☐☐
Date of GROW scan (scan at 35^{+0} to 38^{+0})	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy
Gestation at GROW scan	☐☐+☐ wk+d
Estimated fetal weight at scan	☐☐☐☐ g
Grow centile	☐☐☐.☐

Eligibility

Screening Number	S
Study Number	

1.1. GROW Ethnicity – please tick one only			
British European		Middle Eastern	
Irish European		Indian	
North European		Pakistani	
East European		Bangladeshi	
South European		Chinese	
West European		Other Far East	
North African		South East Asian	
East African		Caribbean	
Central African		Mixed African European	
South African (Black)		Mixed Asian European	
South African (Euro)		Mixed Caribbean European	
West African		Declined	
Other *(Please specify):* _____			

Name of person completing the GROW App data (print name)please note, your name must be on the trial delegation log	
Signature of person completing the GROW App data	
Date Signed	/ / dd/mm/yyyy

Section 1 - Eligibility

Screening Number S

Study Number

2a. Trial inclusion criteria N.B. All boxes must be ticked '**YES**' before proceeding to randomise				
1. Woman aged 18 years or over	Yes		No	
2. Woman with a fetus above 90th customised estimated fetal weight centile on ultrasound scan at 35^{+0} to 38^{+0} weeks gestation	Yes		No	
3. Cephalic presentation	Yes		No	
2b. Trial exclusion criteria N.B. All boxes must be ticked '**No**' before proceeding to randomise				
1. Multiple pregnancy	No		Yes	
2. Breech or transverse lie presentation	No		Yes	
3. Induction of labour contra-indicated	No		Yes	
4. Fetus with known serious abnormality	No		Yes	
5. Home birth or elective caesarean section already planned	No		Yes	
6. Caesarean section or induction indicated due to health conditions such as cardiac disease, epilepsy, or hypertensive disorders	No		Yes	
7. Woman taking medication and/or insulin therapy for diabetes or gestational diabetes	No		Yes	
8. Current diagnosis of major psychiatric disorder requiring antipsychotic medication	No		Yes	
9. Woman unable to give informed consent e.g. learning or communication difficulties that prevent understanding of the information provided	No		Yes	
10. Prisoner	No		Yes	
11. Previous stillbirth	No		Yes	
12. Previous neonatal death (up to 28 days after birth)	No		Yes	
13. Current intrauterine fetal death	No		Yes	

Name of doctor confirming eligibility (print name)please note, your name must be on the trial delegation log	
Signature of doctor confirming eligibility	
Date Signed	/ / dd/mm/yyyy

Recruitment

Screening Number S | | | | | | | | | Study Number | | | | | | | |

Recruitment - Please telephone 02476 150402							
Recruiting site							
Name of researcher performing recruitment							
Recruiting researcher's telephone contact							
Recruiting researcher's email address							
Woman's Date of Birth	D D / M O N / Y Y Y Y						
Woman's GROW Chart ID							
Fetal weight centile	≤95th EFW centile		>95th EFW centile				
Maternal age	≤35 years of age		>35 years of age				
Has an eligibility form been completed and signed for this woman?	No		Yes				
Is the woman still eligible to be included in the trial?	No		Yes				
Has a member from the obstetric team in charge of the participants care confirmed that they are happy for the participant to be recruited (after week 28 of the woman's pregnancy)? (Check Essential Recruitment Checklist)	No		Yes				
Version of Participant Information Sheet provided							
Is gestational age between 35^{+0} and 38^{+0} weeks?	No		Yes				
Has written Informed Consent been obtained?	No		Yes				
Version of Informed Consent signed							
Name of the person who obtained Informed Consent (Please print)							
Study Group	RCT		Cohort: planned elective C-section		Cohort: not requesting an elective C-section		
Study Number allocated at recruitment							
Only complete the following section for women in the Randomised Controlled Trial							
Trial arm allocation (please tick)	**Arm A**: Expectant management						
	Arm B: Booking of induction of labour (38^{+0} to 38^{+4})						
	If in arm B, booked induction date		/		/	dd/mm/yyyy	
	If Induction booked, gestational age at start of planned induction date		+		wk+d		

Signature of person completing the form:	
Date Signed:	/ / dd/mm/yyyy

Section 2 - Baseline

Visit Date ☐☐/☐☐/☐☐☐☐ Study Number ☐☐☐☐☐☐☐☐

1. Current obstetric status				
Gestational diabetes mellitus	Yes		No	
Pregnancy induced hypertension	Yes		No	
Pre-eclampsia	Yes		No	
Other *(if yes please specify):*	Yes		No	

2. Current medical status				
Diabetes mellitus	Yes		No	
Asthma	Yes		No	
Epilepsy	Yes		No	
Essential hypertension	Yes		No	
Heart Disease	Yes		No	
Other *(if yes please specify):*	Yes		No	

3. Tobacco use				
Was the woman a smoker at booking visit?	Yes		No	

4. Alcohol use	
How many units of alcohol did the woman drink per week at the booking visit?	☐☐☐ Units per week

5. Regular Medications				
Is the woman taking any regular medication? *(if 'Yes' please complete the Regular Medication form)*	Yes		No	

6. Corticosteroids				
Did the woman receive a course of antenatal corticosteroids for fetal lung maturation during this pregnancy?	Yes		No	

Baseline

Study Number ☐☐☐☐☐☐☐☐

7. Previous pregnancy information – please complete one row per baby ≥24 weeks

Previous delivery	Year of baby's birth	Was this a multiple birth?	Gestation at delivery (wk+d)	Mode of delivery 1.Vaginal 2.Assisted vaginal 3.Caesarean	Birthweight (g)	Birth centile	Was there shoulder dystocia?	Did the fetus sustain a brachial plexus injury?
1.		Yes ☐ No ☐					Yes ☐ No ☐	Yes ☐ No ☐
2.		Yes ☐ No ☐					Yes ☐ No ☐	Yes ☐ No ☐
3.		Yes ☐ No ☐					Yes ☐ No ☐	Yes ☐ No ☐
4.		Yes ☐ No ☐					Yes ☐ No ☐	Yes ☐ No ☐
5.		Yes ☐ No ☐					Yes ☐ No ☐	Yes ☐ No ☐

Name of person completing the form (print name): please note, your name must be on the trial delegation log	
Signature of person completing the form:	
Date Signed:	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy

Unscheduled hospital visit post randomisation prior to delivery

Visit Date ☐☐/☐☐/☐☐☐☐ Study Number ☐☐☐☐☐☐☐☐

1. Hospital visit pre-delivery – Please complete a form for each unscheduled visit				
Did the woman have an unscheduled hospital visit between randomisation and starting labour? *If 'No' do not complete the rest of the section*	Yes		No	
Attendance number				
Name of the hospital				
Reason for attendance				
Date of visit	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy			
Was the woman admitted?	Yes		No	
Date discharged	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy			

Type of ward	**Number of nights**
Labour ward triage/assessment area	
Maternity unit	
Accident and emergency	
General ward	
High dependence unit	
Intensive care unit	
Other *(Please specify below):*	

2. Adverse Events and Regular Medications				
Has the woman experienced any adverse events since the last visit? *(if 'Yes' please complete the Adverse Event form and/or an SAE form)*	Yes		No	
Has the woman had any changes to regular medications since the last visit? *(if 'Yes' please complete the Regular Medication form)*	Yes		No	

Name of person completing the form (print name)*:please note, your name must be on the trial delegation log*	
Signature of person completing the form:	
Date Signed:	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy

Intra Partum

Visit Date ☐☐/☐☐/☐☐☐☐ Study Number ☐☐☐☐☐☐☐☐

1. Hospitalisation

Date and time woman was admitted to hospital for delivery	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy ☐☐:☐☐ 24 hour clock Not applicable – baby not born in hospital ☐

2. Onset of labour type - Cohort and RCT

Onset of labour type.	Spontaneous	
	Induced	
	No labour (Caesarean section)	

3. Induction – complete only if woman induced

Reason for induction (tick all that apply)	Allocated to induction in trial				
	Post dates				
	Decreased fetal movement				
	LGA				
	Restricted fetal growth				
	Maternal request				
	Other *(Please specify the reason):* _____				
If the woman was induced, method(s) used	Mechanical (Foley catheter)	Yes		No	
	Prostaglandin	Yes		No	
	Artificial rupture of the membrane	Yes		No	
	Oxytocin	Yes		No	
If Oxytocin given, duration	☐☐:☐☐ hh:mm				
Date and time induction started	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy ☐☐:☐☐ 24 hour clock				

Intra Partum

Study Number ☐☐☐☐☐☐☐☐

4. Labour				
Date and time woman admitted to delivery ward	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy ☐☐:☐☐ 24 hour clock			
Date and time first stage of labour started	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy ☐☐:☐☐ 24 hour clock		Not Available	
Was labour augmented?	Yes		No	
If augmented please specify	Artifical rupture of membranes		Oxytocin	
If Oxytocin given, duration	☐☐:☐☐ hh:mm			
Date and time second stage of labour started	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy ☐☐:☐☐ 24 hour clock		Not Available/ Not Applicable	
Date and time active second stage of labour started	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy ☐☐:☐☐ 24 hour clock		Not Available/ Not applicable	

Intra Partum

Study Number ☐☐☐☐☐☐☐☐

5. Delivery

Location of delivery	Labour Ward	☐
	Born before arrival	☐
	Other (Please specify) _____	☐
Presentation at birth *(please tick one)*	Cephalic	☐
	Breech	☐
	Transverse lie	☐
Final mode of delivery *(please tick one)*	Vaginal delivery	☐
	Instrumental delivery -Ventouse	☐
	Instrumental delivery - Forceps	☐
	Instrumental delivery – Rotational forceps	☐
	Elective caesarean section	☐
	Emergency caesarean section (please complete section 5 as far as possible and section7)	☐

Was there an attempt at instrumental delivery? *(please tick all that apply)*	Ventouse	Yes	☐	No	☐
	Forceps	Yes	☐	No	☐
	Rotational forceps	Yes	☐	No	☐
Was instrumental delivery performed in theatre?		Yes	☐	No	☐

Indication for instrumental delivery	Fetal distress	☐
	Failure to progress	☐
	Other *(Please specify the reason):* _____	☐

If delivered vaginally please complete below

Date and time head was delivered	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy	☐☐:☐☐ 24 hour clock
Date and time body was delivered	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy	☐☐:☐☐ 24 hour clock
Date and time of third stage of labour completed	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy	☐☐:☐☐ 24 hour clock
Estimated Blood Loss	☐☐☐☐☐ mls	
Date and time woman left the delivery ward	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy	☐☐:☐☐ 24 hour clock
	Not Applicable – (delivery not in maternity unit) ☐	

Intra Partum

Study Number | | | | | | | | |

6. Shoulder Dystocia				
Was there shoulder dystocia?	Yes		No	
If 'Yes', which of the following manoeuvres were performed? *(Please tick all that apply)*	Mc Robert's position			
	Supra pubic pressure			
	Internal manoeuvres			
	Removing/releasing posterior arm			
	All fours position			
	Cleidotomy (clavicle fracture)			
	Zavanelli manoeuvre			
	Symphysiotomy			

Intra Partum

Study Number ☐☐☐☐☐☐☐☐

7. Caesarean section – Only complete if woman had a caesarean section		
If **elective** caesarean section, reason for caesarean section.	Suspected LGA	
	Maternal choice	
	Other *(Please specify the reason)*	
If **emergency** caesarean section, reason for caesarean section.	Fetal distress	
	Failure to progress first stage	
	Failure to progress second stage	
	Failed instrumentation	
	Other *(Please specify the reason):* _____	
If **emergency** caesarean section; decision to delivery interval.	☐☐ : ☐☐ hh:mm	
Date and time woman admitted to theatre	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy	☐☐ : ☐☐ 24 hour clock
Date and time first anaesthetic for caesarean section given	☐☐/☐☐/☐☐☐☐	☐☐ : ☐☐
Date and time caesarean section was started (knife to skin)	☐☐/☐☐/☐☐☐☐	☐☐ : ☐☐
Date and time of knife to uterus	☐☐/☐☐/☐☐☐☐	☐☐ : ☐☐
Date and time of complete delivery	☐☐/☐☐/☐☐☐☐	☐☐ : ☐☐
Date and time of third stage of labour completed	☐☐/☐☐/☐☐☐☐	☐☐ : ☐☐
Estimated blood loss	☐☐☐☐☐ mls	
Date and time woman left the delivery ward	☐☐/☐☐/☐☐☐☐	☐☐ : ☐☐
Was there difficulty in delivering the shoulders at Caesarean section?	Yes ☐	No ☐

Intra Partum

Study Number | | | | | | | | |

Did the woman receive any pain relief in the time period directly related to delivery of the baby during the in-patient stay? If yes please complete the relevant row(s) below.

Tick if no pain relief given: ☐

8. Pain relief

Type of pain relief					Time Point				Dose	Unit	Number of times administered
Opioid - Pethidine	Yes		No		Ante-partum		Post-partum				
Opioid - Diamorphine	Yes		No		Ante-partum		Post-partum				
Opioid - Meptid	Yes		No		Ante-partum		Post-partum				
Epidural	Yes		No		Ante-partum		Post-partum				
General anaesthetic	Yes		No		Ante-partum		Post-partum				
Spinal anaesthetic	Yes		No		Ante-partum		Post-partum				
Local anaesthetic	Yes		No		Ante-partum		Post-partum				
Pudendal	Yes		No		Ante-partum		Post-partum				
Other *(please specify)* _____	Yes		No		Ante-partum		Post-partum				

Intra Partum

Study Number | | | | | | | | |

Did the woman receive any antibiotics in the time period directly related to delivery of the baby? If yes please complete the row(s) below.

Tick if no antibiotics given: ☐

9. Antibiotics							
Antibiotic Name	**Time Point**				**Dose**	**Unit**	**Route**
	Ante-partum		Post-partum				
	Ante-partum		Post-partum				
	Ante-partum		Post-partum				
	Ante-partum		Post-partum				
	Ante-partum		Post-partum				
	Ante-partum		Post-partum				
	Ante-partum		Post-partum				
	Ante-partum		Post-partum				
	Ante-partum		Post-partum				
	Ante-partum		Post-partum				
	Ante-partum		Post-partum				

Intra Partum

Study Number ☐☐☐☐☐☐☐☐

10. Maternal trauma							
Did the woman have an episiotomy?	Yes		No				
Did the woman sustain a perineal injury?	Yes		No				
If there was perineal injury, please indicate the degree/type	First degree						
	Second degree						
	Third degree	Grade 3a					
		Grade 3b					
		Grade 3c					
	Fourth degree						
Did the woman have a cervical laceration?	Yes		No				
If there was perineal injury, was it repaired?	Yes		No		Not applicable		
If the woman had a repair was the repair undertaken in theatre?	Yes		No		Not applicable		
Date of repair	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy						

Intra Partum

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11. Complications of labour				
Did the woman have a retained placenta requiring manual removal?	Yes		No	
Did the woman have a fever > 38.0 ℃ in labour or within the 24 hours postpartum?	Yes		No	
If the woman did have a fever > 38.0 ℃, what was the peak temperature?	☐☐.☐ ℃		Not applicable	
Did the woman have sepsis in labour or within the 24 hours post-partum ?	Yes		No	
Did the woman die?	Yes		No	
Has the woman had a surgical procedure (unrelated to tears)? *(If yes please specify type of procedure below)* _____	Yes		No	
If the woman had a surgical procedure, please provide the date	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy			

12. Adverse Events and Regular Medications				
Has the woman experienced any adverse events (not already captured on the CRF) since the last visit? *(if 'Yes' please complete the Adverse Event form)*	Yes		No	
Has the woman had any changes to regular medications (not already captured on the CRF) since the last visit? *(if 'Yes' please complete the Regular Medication form)*	Yes		No	

Name of person completing the form (print name)*:please note, your name must be on the trial delegation log*	
Signature of person completing the form:	
Date Signed:	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy

Maternal Post Partum

Visit Date ☐☐/☐☐/☐☐☐☐ Study Number ☐☐☐☐☐☐☐☐

1. Breast feeding						
Did the woman and baby have skin-to-skin contact immediately following birth?	Yes		No		Not applicable	
Did the woman start breast feeding?	Yes		No		Not applicable	
If the woman gave birth in hospital, was the woman still breast feeding at discharge from the ward?			Yes		No	
If breast feeding please specify if this is exclusive or partial					Exclusive	
					Partial	

2.Transfer of woman from labour ward within the same hospital					
Where was the woman transferred to after labour ward? *If 'Home' do not complete the rest of this section 2*		Home		Other Ward	
If 'Other Ward' where was the woman transferred to?		Reason for transfer			Number of nights
Intensive care unit					
High dependency unit (outside labour ward)					
Postnatal ward					
General ward					
Mental health ward					
Other *(Please specify below)* _____					
Date and time discharged from this hospital		☐☐/☐☐/☐☐☐☐ ☐☐:☐☐ dd/mm/yyyy 24 hour clock			
Was the baby discharged to the same address as the mother?		Yes		No	

Maternal Post Partum

Study Number ☐☐☐☐☐☐☐☐

3.Transfer of woman from place of delivery to a different hospital				
Was the woman transferred to a different hospital to the one in which she gave birth? *If 'No' do not complete the rest of this section 3*	Yes		No	
If 'Yes' which hospital was the woman transferred to? *Please provide the hospital name*	_____			

Which ward was the woman transferred to?		Reason for transfer	Number of nights
Intensive care unit			
High dependency unit (outside labour ward)			
Postnatal ward			
General ward			
Mental health ward			
Other *(Please specify below)* _____			
Date admitted to transferred hospital	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy		
Date discharged from transferred hospital	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy		

4. Adverse Events and Regular Medications				
Has the woman experienced any adverse events since the last visit? *(if 'Yes' please complete the Adverse Event form)*	Yes		No	
Has the woman had any changes to regular medications since the last visit? *(if 'Yes' please complete the Regular Medication form)*	Yes		No	

Name of person completing the form (print name):please note, your name must be on the trial delegation log	
Signature of person completing the form:	
Date Signed:	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy

Baby Post Partum

Visit Date ☐☐/☐☐/☐☐☐☐ Study Number ☐☐☐☐☐☐☐☐

1. Baby's outcome						
Outcome at delivery	Live		Stillbirth			
Sex	Female		Male		Indeterminate	
Birth weight	☐☐☐☐ g					
Gestation at birth	☐☐ + ☐ wk+d					
Birthweight customised centile	☐☐☐.☐					
Apgar score at **one** minute	☐☐					
Apgar score at **five** minutes	☐☐					
Apgar score at **ten** minutes	☐☐	Not Taken				
Venous cord pH	☐.☐☐	Not Taken				
Arterial cord pH	☐.☐☐	Not taken				

2. Birth Injuries				
Is the baby recorded as having a humeral fracture?	Yes		No	
Is the baby recorded as having a clavicular fracture?	Yes		No	
Did the baby show signs of brachial plexus palsy?	Yes		No	

Baby Post Partum

Study Number ☐☐☐☐☐☐☐☐

3a. Transfer of baby from labour ward within the same hospital				
Did the baby receive any additional care?	Yes		No	
If 'Yes' principal reason for admission				
Date of admission	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy			

Type of care received	**Number of nights**
Intensive care	
High dependency care (outside labour ward)	
Special care	
Transitional care	
Normal care	
Other *(Please specify below):*	
Date discharged/ transferred ☐☐/☐☐/☐☐☐☐ dd/mm/yyyy	

Baby Post Partum

Study Number ☐☐☐☐☐☐☐☐

3b. Transfer of baby to a <u>different</u> hospital				
Was the baby transferred from the hospital where he/she was delivered? *If 'No' do not complete the rest of this section 3b*	Yes		No	
If 'Yes' which hospital was the baby transferred to? *Please provide the hospital name*				

Type of care (please tick)		Reason for Transfer	Number of nights
Intensive care			
High dependency care (outside labour ward)			
Special care			
Transitional care			
Normal care			
Other *(Please specify below):*			

Date admitted to transferred hospital	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy
Date discharged from transferred hospital	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy

Baby Post Partum

Study Number ☐☐☐☐☐☐☐☐

4. Neonatal procedures and conditions				
Has the baby experienced hypoglycaemia?(A single value < 2.6 mmol/L)	Yes		No	
If 'Yes' what was the lowest blood glucose concentration in the first 24 hours?	☐.☐ mmol/L		Not available	
Did the baby receive intravenous glucose infusion for hypoglycaemia?	Yes		No	
Did the baby have neonatal jaundice requiring treatment?	Yes		No	
Did the baby receive phototherapy?	Yes		No	
If 'Yes', number of days on phototherapy?	☐☐		Not available	
Did the baby receive antibiotics before discharge?	Yes		No	
Has the baby had an ultrasound scan of the brain?	Yes		No	
If 'Yes', result of ultrasound scan	Normal		Abnormal	
Has the baby had an MRI of the brain?	Yes		No	
If 'Yes', result of MRI	Normal		Abnormal	
Has the baby been diagnosed with HIE?	Yes		No	
If HIE has been diagnosed please provide severity. (as defined by the clinician in charge of the baby's care)			Mild	
			Moderate	
			Severe	
Has the baby received therapeutic cooling?	Yes		No	
Has the baby experienced seizure(s) in the first 24 hours?	Yes		No	
Has a congenital abnormality or birth defect been diagnosed at birth e.g. heart disease/chromosome abnormality?	Yes		No	
If 'Yes' please specify:				

Baby Post Partum

Study Number ☐☐☐☐☐☐☐☐

5. Other procedures

Did the baby receive any respiratory support including supplemental O_2?	Yes		No		If 'Yes' Number of days	
Did the baby receive mechanical ventilation (e.g. Endotracheal ventilation)	Yes		No		If 'Yes' Number of days	
Did the baby receive non-invasive respiratory support (e.g. CPAP, or High flow oxygen therapy)	Yes		No		If 'Yes' Number of days	
Did the baby receive Extracorporeal Membrane Oxygenation (ECMO)?	Yes		No		If 'Yes' Number of days	
Did the baby receive Nitric oxide (iNO) therapy	Yes		No		If 'Yes' Number of days	
Did the baby undergo any surgical procedure? *If 'Yes' please specify:* _____	Yes		No			

6. Discharge

Date the baby discharged home	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy		Not applicable	☐
Has the baby died since delivery?	Yes		No	
If the baby has died since delivery, please provide date and time of death and complete an SAE and a 'Notification of Death' form	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy		☐☐ : ☐☐ 24 hour clock	

7. Adverse Events

Has the baby experienced any adverse events since birth? *(if 'Yes' please complete the Adverse Event form)*	Yes		No	
Has the baby received any regular medication? *(if 'Yes' please complete the Regular Medication form)*	Yes		No	

Name of person completing the form (print name):please note, your name must be on the trial delegation log	
Signature of person completing the form:	
Date Signed:	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy

Adverse Event Form

Ongoing log page # ☐ Study Number ☐☐☐☐☐☐☐☐

Did the woman or her baby experience any Adverse Events unrelated to childbirth up to the point of discharge from hospital following randomisation (woman) or delivery (baby)? No ☐ Yes ☐ *(if yes please complete below)*

AE No.	**Adverse Event**	**Who**		**Start Date dd/mm/yyyy**	**Stop Date dd/mm/yyyy**	**Severity** 0 - Mild 1- Moderate 2 - Severe	**Outcome** 0 - Resolved 1- Resolved with sequelea 2 - Not resolved
		Woman			or ongoing ☐		
		Baby					
		Woman			or ongoing ☐		
		Baby					
		Woman			or ongoing ☐		
		Baby					
		Woman			or ongoing ☐		
		Baby					
		Woman			or ongoing ☐		
		Baby					

Please check this box if this is the last page used: ☐

Form Completed by (please print):_____

(Please note your name must be on the trial delegation log)

Signature of person completing the form: _____ Date Signed: ☐☐/☐☐/☐☐☐☐

-

Regular Medication Form

Ongoing log page # ☐ Study Number ☐☐☐☐☐☐☐☐

Did the woman or her baby receive any medication, (other than antibiotic or analgesia during labour) from baseline up to the point of discharge from hospital following delivery? No ☐ Yes ☐ *(if yes please complete below)*

Medication	Who		Start Date dd/mm/yyyy	Stop Date dd/mm/yyyy	Dose	Unit	Route	Indication
1	Woman	☐		or ongoing ☐				
	Baby	☐						
2	Woman	☐		or ongoing ☐				
	Baby	☐						
3	Woman	☐		or ongoing ☐				
	Baby	☐						
4	Woman	☐		or ongoing ☐				
	Baby	☐						
5	Woman	☐		or ongoing ☐				
	Baby	☐						

Please check this box if this is the last page used: ☐

Form Completed by (please print):_____

(Please note your name must be on the trial delegation log)

Signature of person completing the form: _____ Date Signed: - ☐☐/☐☐/☐☐☐☐

Unscheduled ≤30 day neonatal re-admission/neonatal death

Visit Date ☐☐/☐☐/☐☐☐☐ Study Number ☐☐☐☐☐☐☐☐

Please complete one of these forms for each time the baby is re-admitted or transferred to another ward or hospital within 30 days of postnatal discharge. As many 30 day re-admission forms can be used as needed to complete each admission into hospital (even as in-patients). For each separate admission complete a new form

1. Neonatal Death						
Has the baby died since discharge post-delivery?		Yes		No		Unknown
If the baby has died since discharge post-delivery, please provide date and time of death and complete an SAE and a 'Notification of Death' form	☐☐/☐☐/☐☐☐☐ ☐☐:☐☐ dd/mm/yyyy 24 hour clock					
2. 30 day post initial discharge readmission to hospital						
Was the baby re-admitted to hospital within 30 days of initial discharge? *If 'No' do not complete the rest of this section*		Yes		No		Unknown
Admission number						
Was the re-admission related to shoulder dystocia?		Yes		No		
Name of the hospital to which the baby was admitted.	_____					

Type of ward (please tick)		Reason for admission	No. of nights
General paediatric ward			
High dependency unit			
Neonatal unit			
Post natal ward			
Other *(Please specify below)* _____			

How was the baby transported to hospital?	Air ambulance	
	Land ambulance	
	Car	
	Other *please specify* _____	
Date of readmission	☐☐/☐☐/☐☐☐☐	
Date of discharge	☐☐/☐☐/☐☐☐☐	

3. Adverse Events and Regular Medications				
Has the baby experienced any adverse events since the last visit? *(if 'Yes' please complete the Adverse Event form)*	Yes		No	
Has the baby had any changes to regular medications since the last visit? *(if 'Yes' please complete the Regular Medication form)*	Yes		No	

Name of person completing the form (print name):please note, your name must be on the trial delegation log	
Signature of person completing the form:	
Date Signed:	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy

Unscheduled≤30 day maternal re-admission

Visit Date ☐☐/☐☐/☐☐☐☐ Study Number ☐☐☐☐☐☐☐☐

Please complete one of these forms for each time the <u>woman</u> is re-admitted or transferred to another ward or hospital within 30 days of postnatal discharge. As many 30 day re-admission forms can be used as needed to complete each admission into hospital (even as in-patients). For each separate admission start a new set of forms

1. 30 day postnatal discharge readmission to hospital

Was the woman re-admitted to hospital within 30 days of postnatal discharge? *If 'No' do not complete the rest of this section*	Yes		No	
Admission number				
Name of the hospital where woman transferred.	_____			

Which ward was the woman admitted to?		Reason for admission	Number of nights
Labour ward			
Intensive care unit			
High dependency unit			
Postnatal ward			
General ward			
Other *(Please specify below)* _____			

How was the woman transported to hospital?	Air ambulance	
	Land ambulance	
	Critical care ambulance	
	Car	
	Other *please specify* _____	
Date readmitted	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy	
Date discharged	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy	

2. Adverse Events and Regular Medications

Has the woman experienced any adverse events since the last visit? *(if 'Yes' please complete the Adverse Event form)*	Yes		No	
Has the woman had any changes to regular medications since the last visit? *(if 'Yes' please complete the Regular Medication form)*	Yes		No	

Name of person completing the form (print name):please note, your name must be on the trial delegation log	
Signature of person completing the form:	
Date Signed:	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy

End of Trial

Study Number ☐☐☐☐☐☐☐☐

Did the woman complete the trial? *If Yes, please do not complete the rest of the form, just sign and date the form*	Yes		No	
Date of withdrawal	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy			

Main reason for woman's withdrawal (Select main reason)

N.B. The woman may choose not to give her reasons for, or answer any questions about her decision to withdraw; however if the woman is happy to offer this information, please record in the space below.

Woman's decision		
Protocol violation		
Lost to follow-up		
Trial stopped		
Adverse Event		Please specify the Adverse Event:_____
Other		Please specify Other: _____

Woman's Trial Status

N.B. All women withdrawn from the trial should remain on-study for follow-up and sampling purposes, unless the woman has specifically requested to be completely withdrawn from the trial i.e. no follow-up

	Woman	**Baby**
Withdrawn from intervention		
Withdraw from follow-up		
Withdraw from long-term follow-up		

Name of person completing the form (print name):please note, your name must be on the trial delegation log	
Signature of person completing the form:	
Date Signed:	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy

Notification of Death

Study Number ☐☐☐☐☐☐☐☐

Who does this form refer to?	**Baby**		**Woman**	

Date of Death	☐☐/☐☐/☐☐☐☐ d d / m m / y y y y
Cause of Death	
Details of Death	

Was a post-mortem undertaken?	Yes		No	
Place of post-mortem Please specify				
A copy of the post-mortem report is attached		Please initial to confirm		
A Serious Adverse Event Form has been completed		Please initial to confirm		

Name of person completing the form (print name): please note, your name must be on the trial delegation log	
Signature of person completing the form:	
Date Signed:	☐☐/☐☐/☐☐☐☐ dd/mm/yyyy