WAZO GENI

CASE RECORD FORM

The safety and efficacy of packed cord red blood cell transfusion in children with severe anaemia in a Kenyan hospital

KEMRI SSC No. 1215

LSTM REC No. 07.15

ISRCTN66687527

EVENT SUMMARY						
Event	**Timing**	**Date**			**Time**	
		Day	*Month*	*Year*	*Hour*	*Mins*
Transfusion start time						
Mid-transfusion bloods	Start +2 hrs					
Transfusion end time						
Post-transfusion assessment	End + 2 hrs					
Post-transfusion assessment	Start + 24 hrs					
Post-discharge follow-up	Start date + 28 days				Arranged at discharge	

In the event of any queries regarding the completion of this form or the trial protocol, please feel free to contact us at *any* time:

Oliver Hassall	Principal Investigator	Ext. 221	Mob: 0723 495943
Johnstone Thitiri	Trial Co-ordinator	Ext. 501	Mob: 0722 408020

CONTENTS AND INSTRUCTIONS

Contents

General Instructions

- Ensure you are familiar with the definitions of adverse and serious adverse events
- All fields should be completed
- Use a ball point pen and write clearly
- Print name, sign and date where indicated
- Errors ahould be crossed out with a single line. The correction should be made as close to the original as possible and initialled and dated.
- Ensure that adverse events/ serious adverse events are reported fully
- If you have any concerns, do not hesitate to contact Oliver Hassall (PI) or Johnstone Thitiri (Trial Co-ordinator)

WAZO GENI	Patient Initials					Serial Number						Study number					
Case Record Form												W	G				

ELIGIBILITY

Check appropriate boxes with a tick (☑)

Inclusion criteria

These questions must both be answered **YES** *for the child to be eligible for the study*

	YES	NO
1. Is the child aged 12 years or less?	☐	☐
1. Does the child have severe anaemia requiring transfusion? • If aged < 3 months, Hb ≤ 10g/dL • If aged > 3 months, Hb ≤ 4g/dL	☐	☐

Ineligible

Exclusion criteria

If any of the following questions are answered **YES**, *the child is* ***not*** *eligible for the study*

	YES	NO
1. Is the child in coma? • Blantyre Coma Scale score ≤ 2	☐	☐
2. Is the child prostrated? • If unable to sit when well, unable to take enteral feeds (ng/oral) • If able to sit when well, unable to sit	☐	☐
3. Does the child have uncompensated shock?	☐	☐
4. Does the child have compensated shock? • Capillary refill ≥ 3s and/or • Temperature gradient	☐	☐
5. Does the child have respiratory distress? (Deep breathing)	☐	☐
6. Does the child have neonatal jaundice requiring an exchange transfusion?	☐	☐
7. Is the child enrolled in another <u>intervention</u> trial?	☐	☐
8. Does the child have any other marker of clinical severity that would preclude enrolment in the study? (If in doubt, contact study team)	☐	☐

Ineligible

- If **YES**, give below:
- _

Consent

Informed consent must be given before the child can be enrolled in the study

	YES	NO
Has the child's parent or guardian given informed consent for the child to enrol in the study and receive a cord blood transfusion?	☐	☐

Ineligible

I have assessed the patient, checked the inclusion/exclusion criteria and confirmed that informed consent has been given. The patient is eligible for the study.

Name	Sign	Date			Time (24hr)	
				0		
Investigator or nominee	*Investigator or nominee*	*Day*	*Month*	*Year*	*Hour*	*Mins*

WAZO GENI	Patient Initials	Serial Number	Study number
Case Record Form			W G

PRE-TRANSFUSION (0 hrs)

Clinical assessment prior to transfusion

*Admission **to KDH***

Date of KDH admission			Time (24hr)	
Day	*Month*	*Year*	*Hour*	*Mins*

PID Number					

Current clinical problems		Anthropometric data			
1		**Sex**	Male ☐ Female ☐		
2		**Age**	y	m	d
3		**DOB**	-	-	
4		**Weight**	kg	If pre-term infant:	
5		**Length**	cm	Gest. Age	weeks
6		**MUAC**	cm		

Has the child received a blood transfusion previously?	Yes ☐ No ☐
If **yes**, on how many occasions?	previous transfusions

Please give any details below

Date			Details of transfusion reactions, if any
Day	*Month*	*Year*	

Is the child currently receiving any treatment (e.g drug, fluid)?	Yes ☐ No ☐
*If **yes**, give details in the concomitant treatment sheet (Page 9)*	

Axillary Temp *°C*	Pulse Rate *bpm*	Resp Rate *bpm*	O_2 Sats *%*	Air/ O_2 *A/O*	BP Systol *mm Hg*	BP Diastol *mm Hg*	BP Mean *mm Hg*
.							

General Appearance					
Rigors/chills	Yes ☐ No ☐	Urticarial rash	Yes ☐ No ☐	Jaundice	Yes ☐ No ☐
CVS					
Cap refill ≥ 3s	Yes ☐ No ☐	Temp gradient	Yes ☐ No ☐	Liver edge	cm bcm
Chest					
Deep breathing	Yes ☐ No ☐	Basal creps	Yes ☐ No ☐	Wheeze	Yes ☐ No ☐
CNS					
Prostration	Yes ☐ No ☐	BCS score	/ 5	Others (Record below)	Yes ☐ No ☐

Additional findings of note

Name	Sign	Date			Time (24hr)	
Clinician	*Clinician*	*Day*	*Month*	*Year*	*Hour*	*Mins*

POST-TRANSFUSION (End transfusion + 2 hrs)

Clinical assessment (2 hours after end of transfusion)

Date of assessment			Time (24hr)	
Day	*Month*	*Year*	*Hour*	*Mins*

Physical examination

Axillary Temp *°C*	Pulse Rate *bpm*	Resp Rate *bpm*	O_2 Sats *%*	Air/ O_2 *A/O*	BP Systol *mm Hg*	BP Diastol *mm Hg*	BP Mean *mm Hg*
.							

General Appearance					
Rigors/chills	Yes ☐ No ☐	Urticarial rash	Yes ☐ No ☐	Jaundice	Yes ☐ No ☐
CVS					
Cap refill ≥ 3s	Yes ☐ No ☐	Temp gradient	Yes ☐ No ☐	Liver edge	cm bcm
Chest					
Deep breathing	Yes ☐ No ☐	Basal creps	Yes ☐ No ☐	Wheeze	Yes ☐ No ☐
CNS					
Prostration	Yes ☐ No ☐	BCS score	/ 5	Others (Record below)	Yes ☐ No ☐

Additional findings of note

Adverse events

Has there been any evidence of a transfusion reaction?	Yes ☐ No ☐
*If **yes**, ensure adverse event documentation completed (at end)*	

Have there been any adverse events since the last assessment?	Yes ☐ No ☐
*If **yes**, ensure adverse event documentation completed (at end)*	

Concomitant medication

Has there been any change in the child's treatment since the last assessment?	Yes ☐ No ☐
*Tick **yes** if new treatment started or current treatment ceased.* *If **yes**, give details on concomitant treatment sheet (Page 9)*	

Sign and date

Name	Sign	Date			Time (24hr)	
Clinician	*Clinician*	*Day*	*Month*	*Year*	*Hour*	*Mins*

POST-TRANSFUSION (+24 hrs)

Clinical assessment (24 hrs after start of transfusion)

Date of assessment			Time (24hr)	
Day	*Month*	*Year*	*Hour*	*Mins*

Physical examination

Axillary Temp *°C*	Pulse Rate *bpm*	Resp Rate *bpm*	O_2 Sats *%*	Air/ O_2 *A/O*	BP Systol *mm Hg*	BP Diastol *mm Hg*	BP Mean *mm Hg*
.							

General Appearance					
Rigors/chills	Yes ☐ No ☐	Urticarial rash	Yes ☐ No ☐	Jaundice	Yes ☐ No ☐
CVS					
Cap refill ≥ 3s	Yes ☐ No ☐	Temp gradient	Yes ☐ No ☐	Liver edge	cm bcm
Chest					
Deep breathing	Yes ☐ No ☐	Basal creps	Yes ☐ No ☐	Wheeze	Yes ☐ No ☐
CNS					
Prostration	Yes ☐ No ☐	BCS score	/ 5	Others (Record below)	Yes ☐ No ☐

Additional findings of note

Adverse events

Has there been any evidence of a transfusion reaction?	Yes ☐ No ☐
*If **yes**, ensure adverse event documentation completed (at end)*	

Have there been any adverse events since the last assessment?	Yes ☐ No ☐
*If **yes**, ensure adverse event documentation completed (at end)*	

Concomitant medication

Has there been any change in the child's treatment since the last assessment?	Yes ☐ No ☐
*Tick **yes** if new treatment started or current treatment ceased.* *If **yes**, give details on concomitant treatment sheet (Page 9)*	

Sign and date

Name	Sign	Date			Time (24hr)	
				0		
Clinician	*Clinician*	*Day*	*Month*	*Year*	*Hour*	*Mins*

POST-TRANSFUSION (Discharge)

Clinical assessment (At discharge)

Date of assessment			Time (24hr)	
Day	*Month*	*Year*	*Hour*	*Mins*

Physical examination and symptom assessment

Is the child having fevers?	Yes ☐ No ☐

Is the child jaundiced?	Yes ☐ No ☐

Does the child have a rash?	Yes ☐ No ☐
*If **yes**, describe here. Include details of appearance, distribution and associated symptoms*	

Does the child have an enlarged liver?	Yes ☐ No ☐	Liver edge	cm
*If **yes**, note cm below costal margin*			

Are there any other clinical findings of note?	Yes ☐ No ☐
*If **yes**, describe below*	

Additional clinical findings of note

Adverse events

Has there been any evidence of a transfusion reaction since last assessment?	Yes ☐ No ☐
*If **yes**, ensure adverse event documentation completed (at end)*	

Have there been any adverse events since the last assessment?	Yes ☐ No ☐
*If **yes**, ensure adverse event documentation completed (at end)*	

Concomitant and discharge treatment

Has there been any change in the child's treatment since the last assessment?	Yes ☐ No ☐
*Tick **yes** if new treatment started or current treatment ceased **(Include DISCHARGE medication)*** *If **yes**, give details on concomitant treatment sheet (Page 9)*	

Discharge diagnoses

	Diagnosis
1	
2	

Name	Sign	Date			Time (24hr)	
Clinician	*Clinician*	*Day*	*Month*	*Year*	*Hour*	*Mins*

POST-TRANSFUSION (28 days)

Clinical assessment (KEMRI out-patients)

Date of assessment			Time (24hr)	
Day	*Month*	*Year*	*Hour*	*Mins*

Physical examination and symptom assessment

Is the child reported to be having fevers?	Yes ☐	No ☐

Is the child jaundiced?	Yes ☐	No ☐

Does the child have a rash?	Yes ☐	No ☐
*If **yes**, describe here. Include details of appearance, distribution and associated symptoms*		

Does the child have an enlarged liver?	Yes ☐	No ☐	Liver edge	cm
*If **yes**, note cm below costal margin*				

Are there any other clinical findings of note?	Yes ☐	No ☐
*If **yes**, describe below*		

Additional clinical findings of note

Adverse events

Has there been any evidence of a transfusion reaction since last assessment?	Yes ☐	No ☐
*If **yes**, ensure adverse event documentation completed (at end)*		

Have there been any adverse events since the last assessment?	Yes ☐	No ☐
*If **yes**, ensure adverse event documentation completed (at end)*		

Concomitant treatment

Has there been any change in the child's treatment since the last assessment?	Yes ☐	No ☐
*Tick **yes** if new treatment started or current treatment ceased.* *If **yes**, give details on concomitant treatment sheet (Page 9)*		

Sign and date

Name	Sign	Date			Time (24hr)	
Clinician	*Clinician*	*Day*	*Month*	*Year*	*Hour*	*Mins*

CONCOMITANT TREATMENT

This sheet should provide a record of all treatment that the child has received in addition to a cord blood transfusion. It can help determine the cause of adverse and serious adverse events.

It should be updated, where necessary, at every clinical assessment

- **Add current or new treatments and start dates**
- **Leave end date open if treatment still ongoing**
- **If treatments have ceased since the last assessment then fill in end date**
- **One-off treatments have the same start and end date**

Treatment name (Use generic names for drugs)	**Route**	**Date start**			**Date stop**		
		Day	*Month*	*Year*	*Day*	*Month*	*Year*

Checked complete:

Name	**Sign**	**Date**			**Time** (24hr)	
				0		
Investigator or nominee	*Investigator or nominee*	*Day*	*Month*	*Year*	*Hour*	*Mins*

TRANSFUSION OBSERVATIONS

Transfusion observations

To be completed by nursing staff after the post-transfusion observation period

How many cord blood units did the child receive?	1 ☐ 2 ☐

Was frusemide prescribed?	Yes ☐ No ☐

Unit 1

Donor unit ID	Expiry date	Blood group	Volume transfused
-	0		ml

	Date			Time	
	Day	*Month*	*Year*	*Hour*	*Mins*
Transfusion start time					
Transfusion end time					

Was the transfusion completed?	Yes ☐ No ☐

Was a transfusion reaction suspected?	Yes ☐ No ☐
*If **yes**, ensure that MO/CO was informed and adverse event documentation completed*	

Unit 2 Not applicable ☐

Donor unit ID	Expiry date	Blood group	Volume transfused
-	0		ml

	Date			Time	
	Day	*Month*	*Year*	*Hour*	*Mins*
Transfusion start time					
Transfusion end time					

Was the transfusion completed?	Yes ☐ No ☐

Was a transfusion reaction suspected?	Yes ☐ No ☐
*If **yes**, ensure that MO/CO was informed and adverse event documentation completed*	

Name	Sign	Date			Time (24hr)	
				0		
Nurse	*Nurse*	*Day*	*Month*	*Year*	*Hour*	*Mins*

POST-TRANSFUSION (35 days)

Follow-up at home

Date of visit		
Day	*Month*	*Year*

Was the child found at home?	Yes ☐ No ☐
If **no**, where was the child reported to be?	

If the child **was** found at home, was the child seen to be alive?	Yes ☐ No ☐ N/A ☐
Give any details	

If the child **was not** found at home, was the child reported to be alive?	Yes ☐ No ☐ N/A ☐
Give any details	

Name	**Sign**	**Date**			**Time** (24hr)	
Investigator or nominee	*Investigator or nominee*	*Day*	*Month*	*Year*	*Hour*	*Mins*

LABORATORY DATA (1)

Admission/ Pre-transfusion

Date			Time	
Day	Month	Year	Hour	Mins

ND= Not Done

NR= No Result

Haematology		Biochemistry			
RBC	|__| . |__| |__|	GLU	|__| |__| . |__|	pH	|__| . |__| |__| |__|
HGB	|__| |__| . |__|	SOD	|__| |__| |__|	CAL	|__| . |__| |__|
HCT	|__| |__| . |__|	POT	|__| . |__|	**Malaria microscopy**	
MCV	|__| |__| |__|	CRE	|__| |__| |__|	|__|__|__| / 100 WBC	
PLT	|__| |__| |__|	SBR	|__| |__| |__|	|__|__|__| / 500 RBC	

Name	Sign	Date			Time (24hr)	
				0		
Investigator or nominee	*Investigator or nominee*	*Day*	*Month*	*Year*	*Hour*	*Mins*

Mid-transfusion (+ 2 Hours from start of transfusion)

Date			Time	
Day	Month	Year	Hour	Mins

ND= Not Done

NR= No Result

Biochemistry			
SOD	|__| |__| |__|	CRE	|__| |__| |__|
POT	|__| . |__|	CAL	|__| . |__| |__|

Name	Sign	Date			Time (24hr)	
				0		
Investigator or nominee	*Investigator or nominee*	*Day*	*Month*	*Year*	*Hour*	*Mins*

LABORATORY DATA (2)

Post-transfusion (+ 24 Hours from start of transfusion)

Date						Time			
Day		*Month*		*Year*		*Hour*		*Mins*	

ND= Not Done

NR= No Result

Haematology		**Biochemistry**			
RBC	|__| . |__| |__|	GLU	|__| |__| . |__|	pH	|__| . |__| |__| |__|
HGB	|__| |__| . |__|	SOD	|__| |__| |__|	CAL	|__| . |__| |__|
HCT	|__| |__| . |__|	POT	|__| . |__|	**Malaria microscopy**	
MCV	|__| |__| |__|	CRE	|__| |__| |__|	|__|__|__| / 100 WBC	
PLT	|__| |__| |__|	SBR	|__| |__| |__|	|__|__|__| / 500 RBC	

Name	**Sign**	**Date**			**Time** (24hr)	
				0		
Investigator or nominee	*Investigator or nominee*	*Day*	*Month*	*Year*	*Hour*	*Mins*

Follow-up (28 days after transfusion)

Date						Time			
Day		*Month*		*Year*		*Hour*		*Mins*	

ND= Not Done

NR= No Result

Haematology		
RBC	|__| . |__| |__|	
HGB	|__| |__| . |__|	
HCT	|__| |__| . |__|	**Malaria microscopy**
MCV	|__| |__| |__|	|__|__|__| / 100 WBC
PLT	|__| |__| |__|	|__|__|__| / 500 RBC

Name	**Sign**	**Date**			**Time** (24hr)	
				0		
Investigator or nominee	*Investigator or nominee*	*Day*	*Month*	*Year*	*Hour*	*Mins*

LABORATORY DATA (3)

Blood bank data

Child's blood group	

For children less than 4 months of age

Mother's blood group		N/A ☐

How many cord blood units were cross-matched?	1 ☐ 2 ☐

Details of units cross-matched

Donor ID	Expiry date	Pack Weight	Cord Hb	Group	Volume issued
-	0				

Additional investigations of note

Investigation	Date			Result
	Day	*Month*	*Year*	

Name	Sign	Date			Time (24hr)	
				0		
Investigator or nominee	*Investigator or nominee*	*Day*	*Month*	*Year*	*Hour*	*Mins*

ADVERSE EVENTS- DEFINITIONS

Adverse event
Any untoward medical occurrence which may or may not be related to cord blood transfusion

Serious adverse event
Any untoward medical occurrence which may or may not be related to cord blood transfusion, which:

- Is fatal
- Is life-threatening
- Is disabling or incapacitating
- Prolongs hospitalisation
- Results in hospitalisation
- The investigator considers a serious or significant hazard, contraindication, precaution or side-effect

Expected serious adverse events of cord blood transfusion are:

1. **Related to blood transfusion in general**
   Transfusion reaction

2. **Related to cord blood transfusion in particular**
   Citrate toxicity
   Hyperkalaemia

In the event of ANY serious adverse event please contact the study team immediately

Intensity (refers to the *maximum* intensity)

Mild	An event which is tolerated
Moderate	An event sufficiently discomforting to interfere with daily activity
Severe	An event which prevents normal daily activities

Relationship to cord blood transfusion

Not related	The event is definitely not related to cord blood transfusion
Unlikely	There are other more likely causes and cord blood transfusion is not suspected as a cause
Suspected	(Reasonal possibility) A direct cause and effect relationship between cord blood transfusion and the event has not been demonstrated but is possible or likely
Probable	There probably is a direct cause and effect relationship between the event and cord blood transfusion

Please ensure that all adverse events are fully documented

NON-SERIOUS ADVERSE EVENTS (1)

Tick (☑) where appropriate

Adverse event	*AE1*				
	Date			**Time**	
Onset date and time			0		
End date and time			0		
Leave blank if ongoing	*Day*	*Month*	*Year*	*Hour*	*Mins*
Outcome *If died complete SAE form*	Resolved ☐	Ongoing ☐	Died ☐		
Maximum intensity	Mild ☐	Moderate ☐	Severe ☐		
Action with regard to cord blood transfusion	None ☐	Stopped ☐	Interrupted & restarted ☐		
Relationship to cord blood transfusion	Not related ☐	Unlikely ☐	Suspected ☐	Probable ☐	
Corrective therapy	Yes ☐	No ☐			
	Record details in concomitant treatment section				

Name	**Sign**	**Date**			**Time** (24hr)	
				0		
Investigator or nominee	*Investigator or nominee*	*Day*	*Month*	*Year*	*Hour*	*Mins*

Tick (☑) where appropriate

Adverse event	*AE2*				
	Date			**Time**	
Onset date and time			0		
End date and time			0		
Leave blank if ongoing	*Day*	*Month*	*Year*	*Hour*	*Mins*
Outcome *If died complete SAE form*	Resolved ☐	Ongoing ☐	Died ☐		
Maximum intensity	Mild ☐	Moderate ☐	Severe ☐		
Action with regard to cord blood transfusion	None ☐	Stopped ☐	Interrupted & restarted ☐		
Relationship to cord blood transfusion	Not related ☐	Unlikely ☐	Suspected ☐	Probable ☐	
Corrective therapy	Yes ☐	No ☐			
	Record details in concomitant treatment section				

Name	**Sign**	**Date**			**Time** (24hr)	
				0		
Investigator or nominee	*Investigator or nominee*	*Day*	*Month*	*Year*	*Hour*	*Mins*

NON-SERIOUS ADVERSE EVENTS (2)

Tick (☑) where appropriate

Adverse event	*AE3*				
	Date			**Time**	
Onset date and time			0		
End date and time			0		
Leave blank if ongoing	*Day*	*Month*	*Year*	*Hour*	*Mins*
Outcome *If died complete SAE form*	Resolved ☐	Ongoing ☐	Died ☐		
Maximum intensity	Mild ☐	Moderate ☐	Severe ☐		
Action with regard to cord blood transfusion	None ☐	Stopped ☐	Interrupted & restarted ☐		
Relationship to cord blood transfusion	Not related ☐	Unlikely ☐	Suspected ☐	Probable ☐	
Corrective therapy	Yes ☐	No ☐			
	Record details in concomitant treatment section				

Name	**Sign**	**Date**			**Time** (24hr)	
				0		
Investigator or nominee	*Investigator or nominee*	*Day*	*Month*	*Year*	*Hour*	*Mins*

Tick (☑) where appropriate

Adverse event	*AE4*				
	Date			**Time**	
Onset date and time			0		
End date and time			0		
Leave blank if ongoing	*Day*	*Month*	*Year*	*Hour*	*Mins*
Outcome *If died complete SAE form*	Resolved ☐	Ongoing ☐	Died ☐		
Maximum intensity	Mild ☐	Moderate ☐	Severe ☐		
Action with regard to cord blood transfusion	None ☐	Stopped ☐	Interrupted & restarted ☐		
Relationship to cord blood transfusion	Not related ☐	Unlikely ☐	Suspected ☐	Probable ☐	
Corrective therapy	Yes ☐	No ☐			
	Record details in concomitant treatment section				

Name	**Sign**	**Date**			**Time** (24hr)	
				0		
Investigator or nominee	*Investigator or nominee*	*Day*	*Month*	*Year*	*Hour*	*Mins*

NON-SERIOUS ADVERSE EVENTS (3)

Tick (☑) where appropriate

Adverse event	*AE5*				
	Date			**Time**	
Onset date and time			0		
End date and time			0		
Leave blank if ongoing	*Day*	*Month*	*Year*	*Hour*	*Mins*
Outcome *If died complete SAE form*	Resolved ☐	Ongoing ☐	Died ☐		
Maximum intensity	Mild ☐	Moderate ☐	Severe ☐		
Action with regard to cord blood transfusion	None ☐	Stopped ☐	Interrupted & restarted ☐		
Relationship to cord blood transfusion	Not related ☐	Unlikely ☐	Suspected ☐	Probable ☐	
Corrective therapy	Yes ☐	No ☐			
	Record details in concomitant treatment section				

Name	**Sign**	**Date**			**Time** (24hr)	
				0		
Investigator or nominee	*Investigator or nominee*	*Day*	*Month*	*Year*	*Hour*	*Mins*

Tick (☑) where appropriate

Adverse event	*AE6*				
	Date			**Time**	
Onset date and time			0		
End date and time			0		
Leave blank if ongoing	*Day*	*Month*	*Year*	*Hour*	*Mins*
Outcome *If died complete SAE form*	Resolved ☐	Ongoing ☐	Died ☐		
Maximum intensity	Mild ☐	Moderate ☐	Severe ☐		
Action with regard to cord blood transfusion	None ☐	Stopped ☐	Interrupted & restarted ☐		
Relationship to cord blood transfusion	Not related ☐	Unlikely ☐	Suspected ☐	Probable ☐	
Corrective therapy	Yes ☐	No ☐			
	Record details in concomitant treatment section				

Name	**Sign**	**Date**			**Time** (24hr)	
				0		
Investigator or nominee	*Investigator or nominee*	*Day*	*Month*	*Year*	*Hour*	*Mins*

WAZO GENI	Patient Initials	Serial Number	Study number
Case Record Form			W G

SERIOUS ADVERSE EVENTS (1)

Name and designation of person reporting SAE

Name	Designation

Reason for considering this an SAE:

- ☐ Fatal
- ☐ Life-threatening
- ☐ Disabling/ Incapacitating
- ☐ Hospitalisation prolonged
- ☐ Results in hospitalisation
- ☐ Investigator considers serious or significant hazard, contraindication, precaution or side-effect

Tick (☑) where appropriate

Serious Adverse Event	*SAE1*				
	Date			**Time**	
Onset date and time			0		
End date and time			0		
Leave blank if ongoing	*Day*	*Month*	*Year*	*Hour*	*Mins*
Outcome *If died, see below*	Resolved ☐	Ongoing ☐	Died ☐		
Maximum intensity	Mild ☐	Moderate ☐	Severe ☐		
Action with regard to cord blood transfusion	None ☐	Stopped ☐	Interrupted & restarted ☐		
Relationship to cord blood transfusion	Not related ☐	Unlikely ☐	Suspected ☐	Probable ☐	
Corrective therapy	Yes ☐	No ☐			
	Record details in concomitant treatment section				

Assessment
The SAE is probably associated with:

- ☐ The study design or procedures (but not cord blood transfusion itself)
- ☐ Another condition (e.g condition under study, intercurrent illness)
- ☐ An intervention other than cord blood transfusion

Death certification Not applicable ☐

Date of death			Time of death		Place of death	
		0				
					Sub-location or Health Institution	*District*

Immediate cause of death	Antecedent causes	Other significant conditions
a)	b)	
	c)	

Name	Sign	Date			Time (24hr)	
				0		
Investigator	*Investigator*	*Day*	*Month*	*Year*	*Hour*	*Mins*

Now complete the SAE documentation

on the following

page

SERIOUS ADVERSE EVENTS (2)

Abnormal investigations

Investigation	Date			Value	Unit	Normal range
	Day	*Month*	*Year*			

Remarks

Please provide a brief narrative description of the SAE, attaching extra pages if necessary

Name	Sign	Date			Time (24hr)	
				0		
Investigator	*Investigator*	*Day*	*Month*	*Year*	*Hour*	*Mins*

Name	Sign	Date			Time (24hr)	
				0		
Local safety monitor	*Local safety monitor*	*Day*	*Month*	*Year*	*Hour*	*Mins*