CHiP Control of Hyperglycaemia in Paediatric intensive care

Case Report Form (CRF)

Once this CRF is completed (i.e. 30 days after randomisation or upon patient death) please photocopy all data sheets and store in completed CRF file.

The original CRF (including instructions) should be stored in a secure location until the Data Co-ordinating Centre at the LSHTM can arrange collection by courier.

CHiP Site Number: | | |

PICU Admission Date: | | | | | | 2 | 0 | | | (D D M M M Y Y Y Y)

Patient's Initials: | | | | (First Middle Last)

Date of Birth: | | | | | | | | | | (D D M M M Y Y Y Y)

CHiP Study Number:
(as assigned at randomisation) | | | | |

Patient Hospital Number: | | | | | | | | | | |

Consent Form

Please place a COPY of the patient's consent form here.

STUDY SCHEDULE, CHiP TRIAL				
Activity	**Baseline**	**Days after enrolment into study**	**Days after enrolment into study**	**Follow up**
	Pre-study entry	Day 1	Day 2 – Day 30	1 year
Informed consent signed	X			
PIM 2	X			
RACHS 1	Xa			
Insulin Infusion		X	X	
Weight		Xb		
Height		X		
Waist Circumference		X		
Primary diagnosis		X		
Blood glucose		X	Xc	
PELOD		X	X	
Inotrope score		X	X	
Cardiac, Respiratory & Renal,dysfunction		X	X	
Red cell transfusions		X	X	
Antibiotic therapy		X	X	
Enteral carbohydrate, enteral caloric, intravenous carbohydrate and intravenous caloric intake		X	X	
Local labs:				
Plasma creatinine	X	X	X	
Platelets	X	X	X	
WBC	X	X	X	
AST	X	X	X	
Blood cultures		X	X	
Lactate		X	X	
Adverse events		X	X	X
Transfer information			Xd	
Day 30 status			Xe	
Health care resource Questionnaire				Xf
HUI, KOSCHI,CBCL, CRS-R:S questionnaires				Xf

Abbreviations: CRF = case report form; PIM = paediatric index of mortality; RACHS2= Risk Adjusted outcomes for Congenital Heart disease; PELOD = Paediatric Logistic Organ Dysfunction score; WBC = White Blood Cell count; AST = Aspartate Aminotransferase test.

a. Cardiac surgery patients only.
b. Actual if within 10 days of admission, or otherwise give estimated.
c. Record 12 hourly at 06:00 and 18:00
d. Form to be completed upon initial transfer/discharge from study PICU/CICU or death if prior to day 30.
e. To be assessed on Day 30 (by telephone if patient discharged prior to day 30) or on death if prior to day 30.
f. Follow up by Data Co-ordinating Centre – LSHTM

General instructions

Screening period

Potential patients will be screened based on available clinical and laboratory information. Informed consent will be obtained prior to the performance of any study-related procedures.

Patients eligible for enrolment into this study must meet **ALL** the inclusion criteria and **NONE** of the exclusion criteria immediately preceding the time of enrolment into the study.

Patients who do not meet all entry criteria may be continuously re-screened within 5 days of their admission to the PICU/CICU and if they meet **ALL** inclusion and **NONE** of the exclusion criteria at this time, can be entered into the study.

Screening	Pre treatment	Treatment	Post treatment
Consent obtained			
< 16 yrs old needing intensive care treatment, mechanical ventilation, vasoavtive support drugs, arterial line in situ and expected to continue for at least 12 hours	Randomisation procedure – treatment assignment	Tight control or conventional control algorithm commences. Day 1 → Day 30	Follow up at 11 – 12 months by LSHTM DCC
		Day 1	

STUDY ENROLMENT

General instructions for completing the CRF

No field should be left blank.

Use permanent **black ink** when completing.

To make a change in the CRF:

- Cross through the incorrect data with a single line
- Write the new data alongside the old data
- Initial and date the change
- If the reason for the change is not obvious, write the reason for the change alongside it
- Never use correcting fluid

ND (not done) should be used if data are unavailable
NK* (not known) should be used if the data are unknown and every effort has been made to find the data (please justify).
NA (not applicable) should be used if a measure is not required at that time for that patient.
***NOTE**: The use of NK may be queried by LSHTM DCC.

Select option boxes with a tick ☑ Please do **NOT** use a cross ☒.

The form should be signed by all site personnel completing the CRF.

Randomisation Form (Page 1)

CHiP Site Number: ☐☐ **Admission Date:** ☐☐☐☐☐2☐☐☐☐ (D D M M M Y Y Y Y)

Patient's Initials: ☐☐☐ (First Middle Last) **Date of Birth:** ☐☐☐☐☐☐☐☐ (D D M M M Y Y Y Y)

This information should be collected BEFORE starting the web randomisation process.

Inclusion Criteria:

(Tick)	Yes	No
1) Is the patient <16 years of age?	☐	☐
2) Is the patient undergoing intensive care treatment following injury, major surgery or in association with critical illness?	☐	☐
3) Does the patient have an arterial line *in situ*?	☐	☐
4) Is the patient receiving mechanical ventilation? *A patient receiving intermittent positive pressure ventilation via an Endotracheal tube (ETT) or tracheostomy tube.*	☐	☐
5) Is the patient receiving vasoactive support drugs? *Dopamine, dobutamine, epinephrine (adrenaline), norepinephrine (noradrenaline), Milrinone, Vasopressin & Phenylephrine. This does not include anti-arrhythmics, vasodilators, anti-hypertensives & prostaglandin.*	☐	☐
6) Is treatment expected to continue for at least 12 hours?	☐	☐

All the answers to questions 1–6 must be YES to qualify for the study

Exclusion Criteria:

(Tick)	Yes	No
1) Is the patient <36 weeks corrected gestation?	☐	☐
2) Does the patient have diabetes mellitus?	☐	☐
3) Does the patient have an established or suspected diagnosis of an inborn error of metabolism?	☐	☐
4) Is treatment withdrawal or limitation of intensive care being considered?	☐	☐
5) Has the patient been in a PICU for more than 5 days in succession?	☐	☐
6) Has the patient participated in the CHiP study during a previous PICU admission?	☐	☐

All the answers to questions 1-6 must be NO to qualify for the study

Date the informed consent document was signed by parent / guardian: ☐☐☐☐☐2☐☐☐☐ (D D M M M Y Y Y Y)

Please continue onto page 2.

Randomisation Form (Page 2)

Has the patient had cardiac surgery? ☐ Yes ☐ No

If YES:
Was surgery cardiopulmonary bypass? ☐ Yes ☐ No

RACHS1 score: ☐ 1-4 ☐ 5-6

If NO:
PIM2 (for calculation at randomisation—do not use PIM2 calculated earlier):

Systolic blood pressure: ☐☐☐ mmHg

Both pupils fixed and dilated? ☐ Yes ☐ No

FiO2: ☐.☐☐

PaO2 *(arterial blood)*: ☐☐.☐ kPa

Base excess *(capillary or arterial blood)*: ☐☐.☐ mmol/L ☐ +/-

Elective admission? ☐ Yes ☐ No

Recovery post procedure? ☐ Yes ☐ No

Does the child have a: High risk diagnosis? ☐ Yes ☐ No

Low risk diagnosis? ☐ Yes ☐ No

Calculated PIM2 score: ☐☐ %

Has patient been admitted due to traumatic brain injury? ☐ Yes ☐ No

Once the above data have been entered onto the web randomisation site please record the randomisation details below.

CHiP Study Number: ☐☐☐☐

Allocation: Tight Control ☐
Conventional Control ☐

Date of Randomisation: ☐☐☐☐☐2☐☐☐☐ (D D M M M Y Y Y Y)

Time of Randomisation *(24 hr clock)*: ☐☐ : ☐☐

Form completed by: _____ **Date:** ☐☐☐☐☐2☐☐☐☐ (D D M M M Y Y Y Y)

Please enter the data from this form onto the CHiP data entry software.
For instructions on completed CRF procedure please see CRF cover sheet.

Randomisation – instructions

RACHS 1 categories:

LOW RISK CARDIAC SURGERY (categories 1 – 4)
• All other cardiac operations
HIGH RISK CARDIAC SURGERY (categories 5 and 6)
• Tricuspid valve repositioning for neonatal Ebstein anomaly at age <30 days
• Repair of truncus arteriosus with interrupted aortic arch
• All Norwood stage 1 operations

PIM2 score (Paediatric Index of Mortality)

For the purpose of this study the PIM2 score used should be calculated within an hour prior to randomisation, not on admission to the PICU even if that information is already available. The randomisation website has a built in calculator.

1. Record the first systolic blood pressure measured nearest to the time of randomisation. If this information is missing record 120 mmHg
2. Pupillary reactions to bright light >3mm and both fixed = yes other or unknown = no
3. PaO_2 , if unknown record 0
4. Record the FIO_2 at the time of the PaO_2 if oxygen via ETT or headbox. If unknown record 0.
5. Base excess in arterial or capillary blood only, mmol/l. If unknown record 0.

Recovery post procedure

Tick **Yes** if the main reason for the patient's admission to the PICU was to recover from surgery or a procedure (further clarification is given in the rules for PIM2 performance reliability in the trial site file).

LOW RISK DIAGNOSIS	
Asthma is the main reason for PICU admission	Bronchiolitis is the main reason for PICU admission
Croup is the main reason for PICU admission	Obstructive sleep apnoea is the main reason for PICU admission
Diabetic keto-acidosis is the main reason for PICU admission	

HIGH RISK DIAGNOSIS	
Cardiomyopathy or myocarditis	Cardiac arrest preceding PICU admission
Hypoplastic left heart syndrome	Severe combined immune deficiency
HIV infection	Leukaemia or lymphoma after first induction
Liver failure is the main reason for PICU admission	Spontaneous cerebral haemorrhage
Neuro-degenerative disorder	

- Tick **No** if the patient does not have any of the low risk or high risk diagnosis.
- For further information on rules for PIM2 performance reliability please refer to trial site file.

Traumatic Brain Injury

Tick **Yes** if patient was admitted with an accidental or non-accidental traumatic brain injury.
Please tick **No** if there is no traumatic brain injury or if brain injury was a pre-existing condition

Baseline Data

These data are to be collected AFTER the patient has been randomised.

CHiP Site Number: ☐☐ **CHiP Study Number:** ☐☐☐☐

Patient's Initials: ☐☐☐ (First Middle Last) **Date of Birth:** ☐☐☐☐☐☐☐☐ (D D M M M Y Y Y Y)

		Actual	Estimated
Weight:	☐☐☐.☐ **Kg**	☐	☐
Height:	☐☐☐.☐ **cm**	☐	☐
Waist circumference:	☐☐☐.☐ **cm**	☐	☐

The following values should be taken from the data collected closest to the time of randomisation:

Inotrope score: ☐☐

Plasma creatinine: ☐☐☐ **µmol/L**

Blood glucose: ☐☐.☐ **mmol/L**

PELOD Score: ☐☐

Did the patient receive insulin prior to randomisation? ☐ **Yes** ☐ **No**

If YES:

Date of first insulin infusion: ☐☐☐☐☐20☐☐ (D D M M M Y Y Y Y)

Time of first insulin infusion: ☐☐ : ☐☐ *(24 hr)*

Data required by those randomised via RACHS1 score only:

Length of time of Cardiac bypass *(if applicable)*: ☐☐☐ Minutes

Length of time of Cross Clamp *(if applicable)*: ☐☐☐ Minutes

Form completed by: _____ **Date:** ☐☐☐☐☐20☐☐ (D D M M M Y Y Y Y)

Please enter the data from this form onto the CHiP data entry software.
For instructions on completed CRF procedure please see CRF cover sheet.

Baseline Data - instructions

After informed consent has been obtained and the patient has been randomly assigned to receive either conventional treatment or tight control, complete the baseline data as close as possible to the time of randomisation.

WEIGHT AND HEIGHT MEASUREMENTS

An **actual** weight or height can only be recorded if it has been measured within 10 days of the PICU / CICU admission. Otherwise tick **estimated**.

INOTROPE SCORE

Using the table below calculate a score for each inotrope the patient is receiving at the time of randomisation. If a patient is receiving more than one inotrope add all the scores together and record a total inotrope score. (see example)

Dopamine / Dobutamine	**1mcg / kg / min = 1**
Milrinone	**0.1 mcg /kg / min = 1**
Adrenaline / Noradrenaline	**0.01 mcg / kg / min =1**
Total inotrope score = **Dopamine / Dobutamine = mcg / kg / min X 1** **Milrinone = mcg / kg min X 10** **Adrenaline / Noradrenaline = mcg / kg / min X 100**	For example: At a single time point a patient is receiving Dopamine 5mcg / kg / min and Adrenaline 0.06 mcg / kg /min 5mcg/kg/min x 1 = 5 0.06mcg/kg/min x 100 = 6 Total inotrope score = 11

PLASMA CREATININE

Try to collect data as soon as possible AFTER the time of randomisation. However if the nearest data collection point (after randomization) is more than 12 hours after randomisation, record the data point as ND (Not Done), Unless data are available within the 6 hour period preceding randomisation, in which case it would be acceptable to use this information.

PELOD SCORE

Paediatric Logistic Organ Dysfunction Score (PELOD)
At the closest time point to randomisation, record the values for the PELOD variables and then using the PELOD calculator that has been incorporated into the CHiP data entry software, record the PELOD score.

PELOD Scoring

Baseline data and Hospital data

Cardiovascular

Heart rate:			
> or = 12 years	< or = 150	> 150	
< 12 years	< or = 195	>195	
Systolic blood pressure (mmHg):			
< 1 month	> 65	35 - 65	< 35
1 month - < 1 year	> 75	35 - 75	< 35
1 year - < 12 years	> 85	45 - 85	< 45
> or = 12 years	> 95	55 - 95	< 55

Neurologic

Glasgow coma score:			
12 – 15	7 – 11	4 – 6	3
Pupillary reactions:			
Both reactive		Both fixed	

Hepatic

ALT	
< 950 UI / L	> or = 950 UI / L
PT	
< 20 secs	> or = 20 secs

Pulmonary

PaO2/FiO2:	
> 9.3 kpa	< or = 9.3 kpa
PaCO2:	
< or = 11.7 kpa	> 11.7 kpa
Mechanical ventilation:	
No ventilation	Ventilation

Haematologic

WBC:		
> or = 4.5	1.5 – 4.4	< 1.5
Platelets:		
> or = 35	< 35	

Renal

Creatinine:		
< 7 days	< 140 µmol / L	> or = 140 µmol / L
7 days - < 1 year	< 55 µmol / L	> or = 55 µmol / L
1 year - < 12 years	< 100 µmol / L	> or = 100 µmol / L
> or = 12 years	< 140 µmol / L	> or = 140 µmol / L

Contact Details

CHiP Site Number: ☐☐ **CHiP Study Number:** ☐☐☐☐

Patient's Initials: ☐☐☐ (First Middle Last) **Date of Birth:** ☐☐☐☐☐☐☐☐ (D D M M M Y Y Y Y)

Patient's Surname:										
Patient's Forename:										
Sex *(Please tick)*:	☐ **Male** ☐ **Female**									
Patient's Hospital Number:										
Patient's NHS Number: *(If available)*										

Parent / Guardian Details	
Title:	
Surname:	
Forename:	
Relationship to Patient:	
Home Address:	
Post Code:	
Telephone Number Home:	
Mobile:	
Email:	

GP Details	
GP Name:	
Surgery Address:	
Post Code:	
Telephone Number:	
GP Code *(if available)*:	

Form completed by: _____ **Date:** ☐☐☐☐☐2 0☐☐ (D D M M M Y Y Y Y)

Please enter the data from this form onto the CHiP data entry software.
For instructions on completed CRF procedure please see CRF cover sheet.

Hospital Data – instructions

DAY 1 is the day that the patient is enrolled into the study (not all patients will start insulin on day 1).

NOTE: Please be aware that this data collection sheet of the CRF is **3** pages long (sheet 1a, b and c) and covers days 1 – 15. If the patient is still in PICU/CICU after day 15, the data collection sheets for days 16 – 30 can be found at the back of the completed CRFs file.

INSULIN START TIME

Record the time the **first** insulin infusion is commenced following randomisation on the appropriate calendar day.

INSULIN INFUSION RATE – 06:00 hrs and 18:00 hrs

If a patient is receiving insulin, record the rate it is being administered at exactly 06:00 hrs and 18:00 hrs for that calendar day.

AVERAGE INSULIN INFUSION RATE – (average 00:00 – 23:59)

Calculate the average infusion rate over the 24 hour period from 00:00 to 23:59 hrs for that calendar day.

DOCUMENTATION OF INSULIN INFUSION RATE AND AVERAGE INSULIN INFUSION RATE

If a patient never received insulin please use NA. For patients who did receive insulin use NA prior to the time insulin was started, and then from the time the insulin infusion was started use the appropriate rates or zero

MECHANICAL VENTILATION

Mechanical ventilation is defined as: A patient receiving intermittent positive pressure ventilation via an Endotracheal tube (ETT) or tracheostomy tube. Record **Yes** if the patient received this therapy at any point during that calendar day.
Record **No** on any calendar day that no positive pressure ventilation via an ETT tube or tracheostomy tube is given. (The patient does not necessarily need to be extubated).

VASOACTIVE DRUGS

Record **Yes** if a patient receives any dose of dopamine, dobutamine, epinephrine (adrenaline), norepinephrine (noradrenaline), Milrinone, Vasopressin and Phenylephrine for any process during that calendar day.
Record **No** on any calendar day that no vasoactive drugs were given, this includes anti-arrhythmics, vasodilators, anti-hypertensives and prostaglandin.

RENAL REPLACEMENT THERAPY

Renal replacement therapy is defined as: A patient who receives dialysis, peritoneal or haemofiltration.
Record **Yes** if a patient receives this therapy at any point during that calendar day.
Record **No** on any calendar day that no renal replacement therapy was given. Note that the patient does not need to have all catheters for renal replacement therapy removed.

Hospital Data – instructions cont.

BLOOD STREAM INFECTION

Record **Yes** if a positive culture is documented in association with two or more features of systemic inflammation or on any positive blood culture for fungus.

FEATURES OF SYSTEMIC INFLAMMATION : SIRS Criteria
Core temperature of > 38.5 °C or < 36°C
Tachycardia defined as a mean hear rate > 2 SD above normal for age in the absence of external stimulus, chronic drugs, or painful stimuli: or otherwise unexplained persistent elevation over a 0.5 – 4 hour time period OR for children < 1 year old: bradycardia, defined as a mean heart rate < 10th percentile for age in the absence of external vagal stimulus, β blocker drugs, or a congenital heart disease; or otherwise persistent depression over a 0.5 hour time period.
Mean respiratory rate > 2 SD above normal for age or mechanical ventilation for an acute process not related to an underlying neuromuscular disease or the receipt of general anesthesia
Leukocyte count elevated or depressed for age not secondary to chemotherapy induced leucopenia or > 10% immature neutrophils.

Reference: Goldstein, B; Giroir B; Randolph A; Members of the International Consensus Conference on Pediatric Sepsis. Pediatric Critical care Medicine. Vol 6 (1). January 2005. 2-8.

ANTIBIOTICS

Record **Yes** if the patient is receiving antibiotics for any process.
Record **No** on any calendar day that no antibiotic was given

NUMBER OF HYPOGLYCAEMIC EPISODES - MODERATE (< 2.5 mmols) and SEVERE (< 2.0 mmols)

Record the number of hypoglycaemic episodes that occur during that calendar day. If these occur, follow the Serious Adverse Event reporting procedure (SAE).
Each episode should only be recorded once, for example if a patient had a blood glucose of 1.8 mmols this would **only** be recorded as SEVERE (< 2.0 mmols).

SEIZURES

Record whether the patient had a seizure but only if it required pharmacological treatment during that calendar day. If it is considered to be related to the administration of the study drug insulin, follow the Serious Adverse Event reporting procedures (SAE)

ENTERAL CARBOHYDRATE, TOTAL ENTERAL CALORIFIC INTAKE, INTRAVENOUS CARBOHYDRATE and TOTAL INTRAVENOUS CALORIFIC INTAKE

Using the total energy guide for paediatric feeds, calculate the amount of enteral carbohydrate, total enteral calorific intake, intravenous carbohydrate and total intravenous calorific intake the patient received during that calendar day.

Include fluids associated with the administration of continuous intravenous drug infusions.
Do not include fluids used in the preparation of single bolus drug administration.

NOTE: These values can also be calculated using a tool incorporated into the CHiP data entry software.

Hospital Data – instructions cont.

NUMBER OF RED CELL TRANSFUSIONS

Record the number of prescribed red cell transfusions that were administered on that calendar day.

PAEDIATRIC LOGISTIC ORGAN DYSFUNCTION SCORE (PELOD)

Record the worst values available for the PELOD variables between 00:00 hrs and 23:59 hrs of that calendar day.
Use the PELOD calculator incorporated into the CHiP data entry software to calculate the PELOD score.

INOTROPE SCORE

Using the table below calculate a score for each inotrope the patient is receiving at 06:00 hrs. If a patient is receiving more than one inotrope add all the scores together and record a total inotrope score. (see example)

Dopamine / Dobutamine	**1mcg / kg / min = 1**
Milrinone	**0.1 mcg /kg / min = 1**
Adrenaline / Noradrenaline	**0.01 mcg / kg / min =1**

Total inotrope score =	For example: At a single time point a patient is receiving Dopamine 5mcg / kg / min and Adrenaline 0.06 mcg / kg /min
Dopamine / Dobutamine = mcg / kg / min X 1	
Milrinone = mcg / kg min X 10	5mcg/kg/min x 1 = 5
Adrenaline / Noradrenaline = mcg / kg / min X 100	0.06mcg/kg/min x 100 = 6
	Total inotrope score = 11

BLOOD GLUCOSE

Blood glucose levels should be recorded at 06:00 hrs and 18:00 hrs whether or not the patient is receiving insulin therapy and until discharge from the PICU/CICU.
Blood glucose levels should be measured using standard arterial or capillary point of care monitoring.
Samples analysed by hand held glucometers, a blood gas machine or a result from a laboratory sample can be used.
All equipment used for measuring blood glucose samples should be checked for validity, according to normal local practice.

LACTATE

Record the lactate measurement only if it is collected using the same blood sample that was used for the blood glucose measurement. Otherwise record NA (Not Applicable).

Hospital Data (Sheet 1a)

CHiP Site Number: | | **CHiP Study Number:** | | | | **Date of Birth:** D D M M M Y Y Y Y **Patient's Initials:** First Middle Last

	Date			Insulin start time (24 hr clock)		Insulin infusion rate (Units/kg/hr)		Average Insulin infusion rate (Units/kg/hr)	Mechanical ventilation	Vasoactive drugs	Renal replacement	Blood stream infection	Antibiotics
	DD	MMM	YYYY	Hr	Min	06:00	18:00	(00:00–23:59)	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No
Day 1													
Day 2													
Day 3													
Day 4													
Day 5													
Day 6													
Day 7													
Day 8													
Day 9													
Day 10													
Day 11													
Day 12													
Day 13													
Day 14													
Day 15													

Form completed by: _____ **Date:** D D M M M 2 0 Y Y

Please enter the data from this form onto the CHiP data entry software. For instructions on completed CRF procedure please see CRF cover sheet.

Hospital Data (sheet 1b)

CHiP Site Number: | | **CHiP Study Number:** | | | | **Date of Birth:** D D M M M Y Y Y Y **Patient's Initials:** First Middle Last

	Date			Number of hypoglycaemic episodes <2.5 mmol/L	Number of hypoglycaemic episodes <2.0 mmol/L	Seizures	Enteral carbohydrate	Total enteral calorific intake	Intravenous carbohydrate	Total intravenous calorific intake
	DD	MMM	YYYY			Yes/No	g/kg/day	kcal/kg/day	g/kg/day	kcal/kg/day
Day 1										
Day 2										
Day 3										
Day 4										
Day 5										
Day 6										
Day 7										
Day 8										
Day 9										
Day 10										
Day 11										
Day 12										
Day 13										
Day 14										
Day 15										

Form completed by: _____ **Date:** D D M M M 2 0 Y Y

Please enter the data from this form onto the CHiP data entry software. For instructions on completed CRF procedure please see CRF cover sheet.

Hospital Data (sheet 1c)

CHiP Site Number: | | **CHiP Study Number:** | | | | **Date of Birth:** D D M M M Y Y Y Y **Patient's Initials:** First Middle Last

	Date			Number of red cell transfusions	PELOD score	Inotrope score	Blood glucose (mmols/l)		Lactate (mmols/l)	
	DD	MMM	YYYY			06:00	06:00	18:00	06:00	18:00
Day 1										
Day 2										
Day 3										
Day 4										
Day 5										
Day 6										
Day 7										
Day 8										
Day 9										
Day 10										
Day 11										
Day 12										
Day 13										
Day 14										
Day 15										

Form completed by: _____ **Date:** D D M M M 2 0 Y Y

Please enter the data from this form onto the CHiP data entry software. For instructions on completed CRF procedure please see CRF cover sheet.

Transfer Data

CHiP Site Number: ☐☐ **CHiP Study Number:** ☐☐☐☐

Patient's Initials: ☐☐☐ (First Middle Last) **Date of Birth:** ☐☐☐☐☐☐☐☐ (D D M M M Y Y Y Y)

This sheet should be completed upon the patient's initial discharge/transfer from PICU/CICU or upon patient death if prior to day 30.

Is the patient alive? ☐ Yes ☐ No

If NO:

Date of death: ☐☐☐☐☐2 0☐☐ (D D M M M Y Y Y Y) **Time of death:** ☐☐ : ☐☐ *(24 hour)*

Cause of death: _____

If YES:

Has patient been transferred within this hospital? ☐ Yes ☐ No
(Please give details below)

Has patient been transferred to another hospital? ☐ Yes ☐ No
(Please give details below)

Patient's destination upon initial transfer from PICU/CICU (tick one)

☐ **PICU** ☐ **Other acute care hospital**

☐ **CICU** ☐ **Skilled nursing facility**

☐ **HDU** ☐ **Home**

☐ **General Ward** ☐ **Other** (please specify) _____

Details of transfer:

Name of ward: _____

Name of hospital (if to a different hospital): _____

Date of transfer: ☐☐☐☐☐2 0☐☐ (D D M M M Y Y Y Y) **Time of transfer:** ☐☐ : ☐☐ (24 hour)

Form completed by: _____ **Date:** ☐☐☐☐☐2 0☐☐ (D D M M M Y Y Y Y)

Please enter the data from this form onto the CHiP data entry software.
For instructions on completed CRF procedure please see CRF cover sheet.

Day 30 status / transfer summary

LOCATION OF PATIENT AT DAY 30

Tick the box that corresponds with where the patient is located at day 30

TRANSFER SUMMARY

Using the codes found in the table below, record all patient locations from the date the patient was enrolled into the study (day 1) until day 30

CODE		CODE	
1	Acute care hospital	5	PICU
2	General ward	6	Skilled nursing facility
3	HDU	7	Home
4	CICU	8	Other

Day 30 status and transfer summary

CHiP Site Number: ☐☐ **CHiP Study Number:** ☐☐☐☐

Patient's Initials: ☐☐☐ (First Middle Last) **Date of Birth:** ☐☐☐☐☐☐☐☐ (D D M M M Y Y Y Y)

Location of patient at day 30:

☐ **Dead—please give date of death:** ☐☐☐☐☐☐☐☐ (D D M M M 2 0 Y Y) **Time of death:** ☐☐ : ☐☐ *(24 hour)*

☐ **Not discharged from study hospital**

☐ **Other acute care hospital—Please state name:** _____

☐ **Home**

☐ **Lost to follow up**

☐ **Other—please specify:** _____

Summary of admissions/transfers/discharges:

Day	Date of admission/transfer (for day 1 this is date of study enrolment)	Location code	Name of hospital/ care facility patient was admitted/ transferred to	Date of transfer/discharge
1	D D M M M Y Y Y Y			D D M M M Y Y Y Y
	D D M M M Y Y Y Y			D D M M M Y Y Y Y
	D D M M M Y Y Y Y			D D M M M Y Y Y Y
	D D M M M Y Y Y Y			D D M M M Y Y Y Y
	D D M M M Y Y Y Y			D D M M M Y Y Y Y
	D D M M M Y Y Y Y			D D M M M Y Y Y Y
	D D M M M Y Y Y Y			D D M M M Y Y Y Y
	D D M M M Y Y Y Y			D D M M M Y Y Y Y

If extra space is required for summary of admissions/transfers/discharges, please use the 'transfer summary continued' sheet which can be found in the completed CRF file.

Form completed by: _____ **Date:** ☐☐☐☐☐☐☐☐ (D D M M M 2 0 Y Y)

Please enter the data from this form onto the CHiP data entry software.
For instructions on completed CRF procedure please see CRF cover sheet.

Comments and Patient Summary

CHiP Site Number: ☐☐ **CHiP Study Number:** ☐☐☐☐

Patient's Initials: ☐☐☐ (First Middle Last) **Date of Birth:** ☐☐☐☐☐☐☐☐ (D D M M M Y Y Y Y)

Do you have any comments? ☐ **Yes** ☐ **No**

If YES, enter comments below. Do not use abbreviations or symbols.

Was the patient's admission a result of Non-Accidental Injury (NAI)? ☐ **Yes** ☐ **No**

Does the patient have a chronic neuro-developmental disorder? ☐ **Yes** ☐ **No**

The information reported for this patient is accurate and complete:

Investigator signature: _____ **Date:** ☐☐☐☐☐2 0☐☐ (D D M M M Y Y Y Y)

Please enter the data from this form onto the CHiP data entry software.
For instructions on completed CRF procedure please see CRF cover sheet.