ELECTRONIC CASE REPORT FORM

STANDARD OPERATING PROCEDURES

CCCTG
Canadian Critical Care
Trials Group

CIHR IRSC
Canadian Institutes of
Health Research
Instituts de recherche
en santé du Canada

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List of Abbreviations

ACTH	Adrenocorticotropic hormone	**K+**	Potassium
Ax	Axillary (temperature)	**PaCO₂**	Partial pressure of carbon dioxide in arterial blood
BiPAP	Bilevel positive airway pressure	**PaO₂**	Partial pressure of oxygen in arterial blood
BUN	Blood Urea Nitrogen	**PELOD-2**	Pediatric Logistic Organ Dysfunction, Version 2
CPAP	Continuous positive airway pressure	**PICU**	Pediatric Intensive Care Unit
Ca+	Calcium	**PO**	Oral (temperature)
eCRF	Electronic Case Report Form	**PRISM III**	Pediatric Risk of Mortality, Version 3
ER	Emergency Room	**PR**	Rectal (temperature)
Esoph	Esophageal (temperature)	**PT**	Prothrombin Time
ETT	Endotracheal tube	**Q6h**	Every 6 hours
FiO₂	Fraction of inspired oxygen	**Q8h**	Every 8 hours
GCS	Glasgow Coma Scale	**SAE**	Serious Adverse Event
GI	Gastrointestinal	**SOP**	Standard Operating Procedure(s)
GLU	Glucose	**SCC**	Study Coordinating Centre
ID	Identification	**Tymp**	Tympanic (temperature)
IV	Intravenous	**WBC**	White Blood Cells

❖ **Accessing the Electronic Case Report Form (eCRF)**

➢ Website link to the eCRF: https://redcap.cheori.org/.

You must enter your personal login information to access the eCRF. Login information will be assigned to each user by the Study Coordinating Centre (SCC). After you login, you will be taken to the REDCap home page. Click on the "My Projects" tab at the top of the screen, and then select "STRIPES Pilot Study: Steroid Use in Pediatric Fluid and Vasoactive Infusion Dependent Shock". This will take you to project homepage.

To enter data for a new participant, select "Add/Edit Records" from the menu on the left-hand side of the screen. In the next window, enter the new study ID code and press the "Tab" or "Enter" button. To continue entering data for an existing participant, you can choose the participant ID code from the "Complete" or "Incomplete" drop down menus, or enter their ID code and press the "Tab" or "Enter" button.

Total records: **2**	
Incomplete Records (0)	-- select record -- ▼
Complete Records (2)	-- select record -- ▼
Enter a new or existing Subject ID Code	

Alternately, you can select "Record Status Dashboard" and select the appropriate section of the eCRF for an existing participant.

🔲 **Record Status Dashboard (all records)**

Displayed below is a table listing all existing records/responses and their status for every data collection instrument (and if longitudinal, for every event). You may click any of the colored buttons in the table to open a new tab/window in your browser to view that record on that particular data collection instrument. Please note that if your form-level user privileges are restricted for certain data collection instruments, you will only be able to view those instruments, and if you belong to a Data Access Group, you will only be able to view records that belong to your group.

Displaying record "Test01" through "Test02" ▼ of **2** records

Subject ID Code	1. Patient Eligibility Criteria & Enrolment Information	2. General Demographic Baseline Information	3. PICU Admission PRISM III	4. PELOD-2 Organ Dysfunction Score on Admission and Daily Until Off of Vasoactive Agents	5. Duration of Vasoactive Infusions Administered During PICU Admission	6. Admir of Va Agent F Adn
Test01	🟢	🟢	🟢	🟢	🟢	
Test02	🟢	🟢	🟢	🟢	🟢	

❖ **General Information**

➢ Saving Data Entry

Please note that REDCap does NOT save automatically, so it is highly recommended to save as you go along. Scroll down to the bottom of the data entry form to access the three save options:

Save Record:	This will save the data you have entered and take you back to the project homepage.
Save and Continue:	This will save the data you have entered and allow you to continue data entry within the same section of the eCRF.
Save and go to Next Form:	This will save the data you have entered and will take you to the next section of the eCRF.

> Form Status

Sections of the eCRF are denoted in the Record Status Dashboard by coloured circles. These circles also appear along the menu on the left-hand side of the screen once a study participant has been selected. A grey circle means that no data has been entered into the section. Once data has been entered into a section, by default, data forms will be saved as "Incomplete". The drop down menu at the bottom of the page can be used to change the form status to "Unverified" or "Complete". The coloured circles in the Record Status Dashboard will change colour to indicate the status of the eCRF section. Forms that are saved as "Incomplete" will show as a red circle, forms that are saved as "Unverified" will show as a yellow circle, and forms that are saved as "Complete" will show as a green circle.

> Validation of Data Entry Fields

Where applicable, the data entry field has been validated to specify the required data format (e.g. date and time format, number as opposed to text). If you enter a value that is different from what has been validated, you will get a warning screen to inform you that the data you have entered could not be validated because it does not follow the expected format. Entered data must be corrected before you can continue.

Whenever possible, questions have been flagged as required. If data is missing from required data collection fields in a given section, you will receive a warning when you leave the section that data is missing.

For any applicable numerical data (e.g. lab values, medication doses), the data entry field has been validated with an expected range. This is a soft validation, meaning that if you enter a value outside of the expected range, you will be notified but you can still proceed with this value once you have verified that it is correct.

1. Patient Eligibility Criteria & Enrolment Information

1.1. Eligibility Criteria

Complete the inclusion and exclusion criteria checklist. Indicate the type of vasoactive agent(s) administered to the patient. You may select more than one.

Indicate the date and time that the patient met the inclusion criteria (i.e. the date and time that the vasoactive infusion was started). Patients must be enrolled and randomized within 6 hours of this time, and the study drug must be administered within 8 hours.

1.2. Consent and Enrolment

1.2.1. *Enrolment date and time*
The enrolment date and time will be the time that the patient was entered into the computerized randomization system.

Pharmacy status: Record the pharmacy status at the time of patient enrolment (i.e. during pharmacy hours of operation or during pharmacy off-hours).

1.2.2. *Informed consent date and time*
Document the date and time that informed consent was obtained from the person legally authorized to consent. If a patient was enrolled using deferred consent, you would enter the date and time when informed consent was obtained. If your site is using verbal consent, you can enter the date and time that verbal consent was given as long as this is documented in a note to file.

1.2.3. *If informed consent is not obtained*
If informed consent is not obtained for a patient enrolled via deferred consent, record whether or not the legal guardian gave permission for the study team to continue data collection. If continued data collection was refused, record the date and time data collection stopped. This would be the time when the legal guardian stated their refusal.

2. General Demographic Baseline Information

2.1. Patient Age

Record patient age according to the following guidelines:

If the patient is <1 week	Record age in days only
If the patient is <1 month	Record age in weeks only
If the patient is <1 year	Record age in months only
If the patient is ≥1 year	Record age in years and months

2.2. Patient Weight

Record the weight (in kilograms) as close to time of study enrolment as possible.

2.3. Hospital Admission Date and Time

Record the date and time of admission to your hospital. If the patient was admitted to another hospital, and then transferred to your site, please still record that date and time of admission at your site.

2.4. PICU Admission Date and Time

Record the date and time that the patient was admitted to the PICU. If the date and time of admission is not clearly recorded at your site, use the date and time of the first vital signs in the PICU as the admission date and time.

2.5. Chronic Pre-Existing Medical Conditions

Chromosome/Genetic abnormality
- Indicate whether the patient has a known syndrome, genetic or chromosomal abnormality.
- E.g. Trisomy 21, 22q11 microdeletion

Neurologic Disease:
- E.g. seizure disorder, hydrocephalus

Chronic Lung Disease
- Example of lung diseases of interest include: Bronchopulmonary Dysplasia (BPD), asthma, pulmonary hypertension.
- If the patient has been diagnosed with any chronic lung disease, by a physician, indicate yes to this question.
- BPD is usually diagnosed in individuals who are born prematurely with a consistent chest x-ray, and persistent oxygen need after 36 weeks of gestation (and 4 weeks of life).
- Asthma is usually diagnosed in individuals who have recurrent episodes of cough, shortness of breath, and wheeze. These individuals usually show improvement with bronchodilators and are treated with daily inhaled corticosteroids.

Endocrine
- E.g. diabetes, thyroid abnormality
- Diabetes – Indicate yes if the patient requires daily insulin for glucose control.
- Thyroid – Indicate yes if the patient requires daily thyroid replacement.
- Adrenal insufficiency – Indicate yes if the patient has either been diagnosed by bloodwork (cortisol) and/or requires regular steroid medications.

GI Disease
- Examples of GI conditions of interest include: Crohn's, Colitis, Celiac, Short Gut Syndrome, Protein Losing Enteropathy and other malabsorptive states.
- Indicate yes if the patient has been diagnosed by a physician with any of the above conditions. If the patient has not been tested, record no.
- Includes Liver Disease:
  - Indicate yes if the patient has been diagnosed by a physician with hepatic dysfunction.
  - Indicate yes if the patient (> 30 days of life) has a total bilirubin level that is persistently elevated above normal.
  - Indicate yes if the patient has an International Normalized Ratio (INR) or Partial Thromboplastin Time (PTT) that are both persistently elevated 50% (e.g. INR of 1.5) above normal.

Renal Disease
- Renal diseases of interest would include renal insufficiency and renal tubular acidosis.
- Indicate yes for renal tubular acidosis if the patient has previously been diagnosed by a physician (if they have never been tested indicate no).
- Indicate yes for renal insufficiency if one or more of the following conditions apply:
  - A serum creatinine greater than two times the upper limit of normal
  - Need for dialysis and/or hemofiltration

Musculo-skeletal disease
- E.g. CP, myopathy

Rheumatological Disease
- E.g. Systemic lupus erythematosus (SLE)

Physciatric Disorder
- E.g. autism, ADHD, anxiety

Chronic Infection
- Record the type of chronic infection in the space provided

Congenital Heart Disease
- Any cardiac malformation (corrected or uncorrected) that is present at birth

Other medical condition
- Record any other medical conditions that are present on the chart.

3. PICU Admission PRISM III Score

Complete the PRISM III score using values obtained during the first 12 hours of PICU admission. If multiple values are available, use the most abnormal score during the above time period. For each part of the PRISM III score, you will be asked whether a given value is applicable. Select "Yes" if the value is available. Select "No" if the value is not available and/or if the value does not apply to the patient.

Systolic Blood Pressure
- Use data from an arterial line if available and functioning. Use data collected by a cuff if arterial line is not available or if not functioning properly (i.e. dampened waveform).
- Generally, a cardiac arrest involves more than 30 seconds of cardiac massage. For resuscitation with chest compressions and absent blood pressure, record the systolic blood pressure as "0".
- Do not assess heart rate during crying or iatrogenic agitation

Heart Rate
- For resuscitation with chest compressions and asystole, record the heart rate as "0".
- Do not assess heart rate during crying or iatrogenic agitation.

Temperature
- Record temperature in degrees Celsius.
- Use rectal (PR), oral blood (PO), axillary (ax), esophageal (esoph), tympanic (tymp) or bladder temperature. Specify the temperature route when prompted.

Pupillary Reflex/Mental Status
- Include coma status (Glasgow Coma Scale) if patient has known or suspected acute neurologic disease (i.e. head trauma) or if there is reasonable possibility that acute neurologic disease is present. There must be a reasonable medical condition accounting for the neurologic dysfunction.
- Do not include "chronic coma" or coma caused by drugs.
- Do not include scores for at least 2 hours following anesthesia, sedation or paralysis.
- Do not include "sleeping" as coma.

- If the patient has been iatrogenically sedated or paralyzed during the entire PICU observation period, then use the most recent, accurate mental status assessment prior to the PICU admission (i.e. Emergency department, or if directly admitted to the PICU, use the pre-hospital assessment).
- Pupils must be greater than 3 mm to qualify as fixed and dilated.
- Pinpoint pupils are not included.
- Unequal pupils must be a minimum of 1 mm difference.
- Do not score chronically altered pupils from previous disease or pupils altered by drugs such as atropine.

Blood Gas/Acid Base
- pH and PCO_2 may be obtained from arterial, venous, or capillary blood gas samples.
- Do not use PCO_2 samples obtained during brain death apnea testing.
- Total CO_2 is obtained from the measured sample (done with electrolytes) and NOT the blood gases. However, if your laboratory does not calculate the measured Total CO_2, use the bicarbonate value from the blood gas.

PaO_2
- Use arterial measurements only.

Glucose
- Record the highest value.
- Specify whether the value is recorded in mmol/L or mg/dL.
- Avoid hemolyzed specimens.

Potassium
- Record the highest value.
- Avoid hemolyzed specimens.

Creatinine
- Record the highest value.
- Specify whether the value is recorded in umol/L or mg/dL.
- Avoid hemolyzed specimens.

Blood Urea Nitrogen (BUN)
- Record the highest value.
- Specify whether the value is recorded in mmol/L or mg/dL.

WBC and Platelets
- Record the lowest value.
- Avoid hemolyzed specimens.

PT or PTT
- Record the highest value.

Other factors
- Indicate all that apply or select "None"
- Non operative CV disease includes acute cardiac and vascular conditions as the primary reasons for admission. Cancer and chromosomal anomalies are acute or chronic. Previous

ICU admission and pre-ICU CPR refer to the current hospital admission. CPR requires cardiac massage. Post-operative is the initial 24 hours following an OR surgical procedure. Catheterizations are not post-operative. Acute diabetes includes acute manifestation of diabetes (ie DKA) as the primary reason for ICU admission. Admission from routine care area includes all inpatient locations except the operating or recovery room.

NOTE REGARDING DATA COLLECTION DURING PICU ADMISSION

1. **Please use midnight to midnight as the 24 hour schedule for all PICU data collection <u>unless otherwise noted</u>.**

2. **If patient is discharged from the PICU, and then re-admitted:**

   o **If re-admitted in ≤ 24 hours, this is considered the same PICU admission and data collection would continue**

   o **If patient is re-admitted > 24 hours later, this is considered a separate PICU admission and data collection would not continue following re-admission**

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4. **PELOD-2 Score on Admission and Daily Until off of Vasoactive Agents**

Record the PELOD-2 score at PICU admission (Day 1) and on Days 2-7 until the patient is off of all vasoactive agents. If vasoactive agents are stopped before Day 7, you do not need to continue collecting the PELOD-2 score for the remaining days. If a value is measured more than once in a given day, enter the most abnormal value. Please use midnight to midnight as the 24 hour schedule.

For scoring purposes: when a variable is not measured it is assumed to be either identical to the last measurement (if the physician considers that the value of the variable did not change) or normal (if the physician considers that the value is normal).

Glasgow Coma Scale (GCS)
- Assess only patients with known or suspected acute central nervous system disease.
- Use the lowest value.
- If sedated, paralysed or intubated, record the estimated GCS before these events.

Pupils
- Non-reactive pupils must be > 3 mm.
- Do not assess during crying or after iatrogenic pupillary dilatation.

Heart rate and mean arterial pressure
- Do not assess during crying or iatrogenic agitation.

PaO_2/FiO_2 ratio
- Use the arterial measurement of PaO_2 only.
- PaO_2/FiO_2 ratio is considered normal in children with cyanotic heart disease.
- FiO_2 = Fraction of inspired oxygen.

- The PaO_2 and FiO_2 values entered in the CRF must be measured at the same time. Use values that result in the lowest PaO_2/FiO_2 ratio.

PaCO$_2$
- May be measured from arterial, capillary, or venous samples.

Invasive Ventilation
- The use of mask ventilation is not considered invasive.

5. Duration of Vasoactive Infusions Administered During PICU Admission

Record if the patient received any of the vasoactive infusions listed at any time during PICU admission. If you indicate that a given vasoactive infusion was administered, you will be prompted to provide the start date and time, and stop date and time. If a vasoactive infusion was stopped and then restarted within 6 hours, please include this period in the total duration. If a vasoactive infusion was stopped and then restarted after more than 6 hours, please record this second period in the "Other Vasoactive Infusion" section provided.

Example: On 24 May 2014, patient is started on dopamine at 10:00. The infusion is stopped at 13:00, restarted at 14:00, and stopped at 19:00. The start date & time for this patient would be entered as 24 May 2014 10:00 and the stop date & time would be entered as 24 May 2014 19:00.

Example: On 24 May 2014, patient is started on dopamine at 10:00. The infusion is stopped at 13:00. Dopamine is restarted at 20:00, and stopped at 23:00. This would be entered as two administrations. The first start date & time and stop date & time would be entered as 24 May 2014 10:00 to 24 May 2014 13:00 under Dopamine. The second start and stop date & time would be entered as 24 May 2014 20:00 to 24 May 2014 23:00 under "Other vasoactive infusion".

If you are entering data under "Other vasoactive infusion", please indicate the type of vasoactive infusion administered.

If the patient did not receive vasoactive infusions during PICU admission, please check "N/A". Note that since being on a vasoactive infusion for 1-6 hours is an inclusion criteria for this study, if you indicate N/A, you will be prompted to verify that the patient met the inclusion criteria for this study and to explain your verification.

If the patient goes to the OR during PICU stay, continue recording any vasoactive infusions given in the OR.

6. Daily Administration of Vasoactive Agents During PICU Admission

For each day of PICU admission, record if vasoactive agents were administered, and the specific type(s) of agent(s) used. Please use midnight to midnight as the 24 hour schedule. Day 1 is the day of patient enrolment (i.e. the date that patient met eligibility). Record information on vasoactive agents up to Day 8 of PICU admission or until PICU discharge, whichever occurs first. If the patient was given any type of vasoactive agent that day, select "Yes". If the patient did not receive vasoactive agents that day, and is still admitted to the PICU, check "No". If the patient did not receive vasoactive agents that day, and is no longer admitted to the PICU, please check "Patient has been discharged".

For each vasoactive agent administered during PICU admission, indicate the highest daily dose. Please pay attention to the required number of decimal places for each dose. This information is specified below the data entry field.

If the patient did not receive any vasoactive agents during PICU admission, check "N/A". Note that since being on a vasoactive infusion for 1-6 hours is an inclusion criteria for this study, if you indicate N/A, you will be prompted to verify that the patient met the inclusion criteria for this study and to explain your verification

If the patient goes to the OR during PICU stay, continue recording any vasoactive infusions given in the OR.

7. Fluid Bolus and Intake/Output

7.1. Total Fluid Received Prior to Enrolment
Record the total amount (in mL) of fluid received from 6 hours prior to the start of the first vasoactive infusion up until the time of enrolment into the study (i.e. time of randomization). Record all IV fluid received including maintenance, antibiotics, other medications, and blood products. If any of the fluids listed were not administered, please enter "0".

If fluid(s) were administered that are not listed, indicate the total mL under "Other - Amount of fluid received". A text box will appear if a number >0 is entered in the "Other – Amount of fluids received" data field. List the other type(s) of fluid administered in this text box.

7.2. Fluid Intake and Output
Record the total fluid intake and output for Day 1 to Day 7 (or until discharge, whichever occurs first). Day 1 is the day the patient was enrolled into the study. **For this section, please use the 24 hour schedule in use at your institution.** Day 1 fluid starts from the time of enrolment into the study until the end of that day as per your institution's 24 hour schedule (e.g. I/O calculated at your institution from 7am to 7am, then Day 1 would be from time of enrolment until 7am).

Fluid intake includes the following: all parenteral and enteral fluids and blood products administered to the patient, fluid input from extracorporeal circuits (e.g. renal replacement therapy, plasmapheresis). For each day, indicate the combined total fluid intake in millilitres.

Fluid output includes the following: urine, stool, blood loss, draining of bodily fluids in chest tubes and other drains, fluid output from extracorporeal circuits (e.g. renal replacement therapy, plasmapheresis). For each day, indicate the combined total fluid output in millilitres.

If the patient goes to the OR during PICU stay, include any fluid intake & output from the OR in the daily totals.

8. Daily Mechanical Ventilation

Indicate if the patient was mechanically ventilated at any time during Day 1 to Day 28 of PICU admission. Day 1 is the day of patient enrolment (i.e. the day that the patient first met eligibility criteria for the study).

Record the **initial** start date and time of mechanical ventilation and the **final** stop date and time of mechanical ventilation. If the patient was extubated and re-intubated between the initial start date and time and the final stop date and time, record the dates and times of these events. Space has been provided to record the date and time of up to 3 extubation & re-intubation events. If the patient was extubated and re-intubated more than 3 times, record information on the first 3 occurrences.

<u>Mechanical ventilation includes</u>: any form of invasive ventilation. Do not include non-invasive ventilation (i.e. CPAP, BiPAP) in this section.

9. **Daily Acute CPAP or BiPAP Ventilation**

Indicate if the patient received non-invasive ventilation (CPAP or BiPAP) at any time during Day 1 to Day 28 of PICU admission. Day 1 is the day of patient enrolment (i.e. the day that the patient first met eligibility for the study).

Record the **initial** start date and time of CPAP/BiPAP and the **final** stop date and time of CPAP/BiPAP. If CPAP/BiPAP was stopped and re-started >6 hours later during the time between the initial and the final stop date & time, please record the dates and times that CPAP-BiPAP was stopped and re-started. Space has been provided to record the date and time of up to 3 stop and re-starts. If the CPAP/BiPAP was stopped and re-started >6 hours later on more than 3 occasions, record information on the first 3 occurrences.

If CPAP/BiPAP was stopped and re-started in < 6 hours, do not record any information about this event.

10. **Research Blood Sampling and Adrenal Testing**

10.1.   Research Blood Sampling

Indicate whether a research blood sample was obtained. If a sample was collected, indicate the date and time of collection, and whether or not the patient was on study drug at the time the sample was collected. The SCC will enter the lab results for the research samples at the end of the study.

10.2.   Clinically-Indicated Cortisol Level

Record if the patient had a random cortisol level done as part of clinical care. If a sample was done, record the date and time of collection, and the cortisol level result.

10.3.   ACTH Stimulation Test

Indicate if the patient had an ACTH stimulation test done during hospital admission as part of clinical care. If yes, indicate the date and time the test was done, the cortisol level post-ACTH in nmol/L, and the time of the post-ACTH cortisol level.

11. **Use of Ranitidine, Pantoprazole or Lanzoprazole**

Indicate whether the patient received Ranitidine, Pantoprazole, or Lanzoprazole prior to enrolment, at any time during PICU admission, and if study drug was given at any time while the patient was on one of the above medications.

Start and Stop Time: Indicate the **initial** start time and the **final** stop time for each of these medications. If the medication was started, stopped and restarted at any time during PICU course, use the first date and time the medication was started and the last date and time that the medication was stopped.

E.g. Patient was initially started on Ranitidine on 11-Mar-2014 at 10:00am and stopped on 13-March-2014 at 14:00. Ranitidine was restarted on 14-March-2014 at 9:00am and finally stopped on 16-March-2014 at 17:30. The start and stop date/times for Ranitidine entered into the eCRF would be:

- Start: 11-March-2014 10:00
- Stop: 16-March-2014 17:30

Discharge: If the patient is discharged while still on Ranitidine, Pantoprazole or Lanzoprazole, use the date and time of discharge as the medication stop date/time.

12. Red Blood Cell Transfusions and Hemoglobin

Record if the patient was given a red blood cell transfusion for each day, up to 8 days, that the patient is on study drug. Day 1 is the day of patient enrolment (i.e. the day that the patient first met the study eligibility criteria). Please use midnight to midnight as the 24 hour schedule.

For Day 1 to Day 8 indicate "Yes" if the patient is on study drug and a transfusion was given. Indicate "No" if a transfusion was not given that day and the patient is still on study drug. If study drug has been stopped or the patient has been discharged from the PICU, indicate "Study drug stopped/Discharged".

If the patient goes to the OR during PICU stay, record any RBCs given in the OR.

If available, enter the lowest hemoglobin value observed on Day 1 to Day 8.

13. Gastrointestinal Bleeding

Record any form of gastrointestinal bleeding that occurred during each day of PICU admission (up to Day 28 or discharge). For Days 1-28, indicate "Yes" if any signs of GI bleeding were observed that day. Indicate "No" if there were no signs of GI bleeding that day and the patient is still admitted to the PICU. Indicate "Discharged" once the patient is discharged from the PICU.

If GI bleeding is observed within the same 24 hour period as PICU discharge, select "Yes" and on the following day indicate "Discharged".

Day 1 is the day of patient enrolment (i.e. the day that the patient first met the study eligibility criteria). Please use midnight to midnight as the 24 hour schedule.

GI Bleeding includes any of the following: coffee ground emesis, coffee grounds in nasogastric tube, melena stools, and blood in diaper etc. as documented in the nurse's notes or other progress notes.

14. Daily Insulin Infusion

Record if the patient was on an insulin infusion for each day that the patient is on study drug (up to Day 8). For each day, indicate "Yes" if the patient was on an insulin infusion + study drug. Indicate "No" if the patient was not given an insulin infusion that day and is still on study drug. Once study drug is stopped, indicate "Study drug stopped". Subsequent days will appear if "Yes" or "No" are selected for the previous day. Once you have indicated "Study drug stopped", all proceeding days will remain hidden and no further data entry is required for this section. If an insulin infusion is administered within the same 24 hour period that study drug is stopped, select "Yes" and on the following day indicate "Study drug stopped".

Day 1 is the day of patient enrolment (i.e. the day that the patient first met the study eligibility criteria). Please use midnight to midnight as the 24 hour schedule.

If an insulin infusion was given, record the start and stop time of the infusion. If multiple insulin infusions were given that day, record the start and stop time of the first two infusions. If the patient was on an insulin infusion for the entire day, please record 0:00 as the start time and 23:59 as the stop time.

15. Lab Results

15.1. WBC, GLU and Ca+ Results

15.1.1. Baseline
Record baseline white blood cell (WBC), glucose (GLU) and calcium (Ca+) lab results. Use the lab results closest to the time of patient enrolment, but prior to patient enrolment. Patient enrolment is the time that the patient was entered into the computerized randomization system. You may use lab results prior to PICU admission (i.e. Emergency Department or ward) if the patient met the eligibility criteria on PICU admission or just prior to PICU admission. If no lab results are available prior to enrolment, indicate "No" to the first question. If lab results prior to enrolment are available for WBC, GLU and/or Ca+, indicate "Yes" to the first question. Enter the date and time of the test, the specific result types available, and applicable lab results. Please note the required number of decimal places for WBC, GLU and Ca+ (noted under the data entry field).

15.1.2. Test #1 - #30
Enter any WBC, GLU and/or Ca+ results available for the first 72 hours post-enrolment. For each Test (#1-30) you will be asked to enter the date and time of the test, the type of results that are available, and to enter the results. Please note the required number of decimal places for WBC, GLU and Ca+ (noted under the data entry field). After the first test, subsequent tests will not appear unless you indicate that additional results are available for the 72 hour period post-enrolment.

Space has been provided to enter lab results up to 30 times for the 72 hour period. If additional tests were done during these 72 hours, record results from the first 30 tests.

Calcium: Use ionized calcium, adjusted to pH if available

GLU: Record the result in mmol/L.

15.2. Albumin, Urea, and Creatinine Lab Results

Record albumin, urea and creatinine results at baseline (prior to enrolment), and for the first 7 days following patient enrolment. If no albumin, urea, or creatinine results are available for a given day, indicate "No". Day 1 is the day that the patient was enrolled into the study (i.e. the day that the patient first met the study eligibility criteria). Please use midnight to midnight as the 24 hour schedule.

Albumin: If multiple albumin results are available for a given day, use the **lowest** value observed.

Urea: If multiple urea results are available for a given day, use the **highest** value observed.

Creatinine: If multiple creatinine results are available for a given day, use the **highest** value observed.

Baseline Results: Use the lab results closest to the time of patient enrolment, but prior to patient enrolment. The time of patient enrolment is the time that the patient was entered into the computerized randomization system. You may use lab results prior to PICU admission (i.e. Emergency Department or ward) if the patient met the eligibility criteria on PICU admission or just prior to PICU admission.

16. Cultures and Antibiotics

16.1. Antibiotics in the Emergency Room

Indicate if the patient was administered antibiotics in the ER. If the patient did not receive antibiotics, or was never in the ER, indicate "No". If antibiotics were given, indicate "Yes", then enter the number of different antibiotics given, and list the specific types.

16.2. Cultures and Antibiotics during PICU Admission

16.2.1. Cultures
For each day of PICU admission (up to Day 28 or discharge), indicate if a culture was sent. Indicate "Yes" if a culture was sent that day, indicate "No" if a culture was not sent that day and the patient is still admitted to the PICU, and enter "Discharged" once the patient is discharged from the PICU.

If a culture was sent, indicate if the results were positive. For positive results, indicate the total number of positive culture sites and indicate the site(s) (e.g. skin, respiratory/ETT, blood, urine, other), and the type of organism(s) grown.

16.2.2. Antibiotics
For each day of PICU admission, indicate if the patient was on antibiotics. If antibiotics were given, record the number of different antibiotics given, and list the specific types.

17. Outcome Information

Enter the date and time of PICU discharge and hospital discharge. Record patient status at PICU and hospital discharge as "Alive" or "Dead".

If the patient died while in the PICU, use the date and time of death as the PICU and the hospital discharge date and time. If the patient died after discharge from the PICU, but prior to discharge from hospital, use the date and time of death as the hospital discharge date and time.

If the patient was discharged and re-admitted within ≤24 hours, this is considered the same admission. Use the date and time of <u>final</u> discharge in the eCRF (i.e. discharge date & time following the re-admission).

If the patient was discharged and re-admitted >24 hours later, this is considered a separate admission and information on the re-admission would not be included in the eCRF.

18. Study Drug

Indicate if the patient was administered the study drug. If yes, indicate the <u>initial</u> start date and time and the <u>final</u> stop date and time of study drug. If no, please record the reason(s) why study drug was not administered. Do not include open-label steroids in the above timeframe.

Indicate the dosing frequency used on each day (i.e. bolus dose, every 6 hours (q6h), or every 8 hours (q8h). You can enter more than one dosing frequency for a given day. Record the total number of doses given that day at each applicable dosing frequency.

Day 1 is the day of patient enrolment (i.e. the day that the patient first met eligibility criteria for the study). Please use midnight to midnight as the 24 hour schedule.

If the patient is no longer on study drug, indicate "No" for all remaining days.

19. Unblinding and Open-Label Steroid Use

19.1.   Open-Label Steroid Use during PICU Admission

Indicate if open-label hydrocortisone was used following patient enrolment. If yes, indicate the date and time of open-label hydrocortisone use, and the number of doses.

19.2.   Patient Status at Time of Open-Label Steroid Use

Enter any available information about the patient's status at the time of open-label hydrocortisone use.

19.3.   Unblinding

Indicate if the treating physician requested unblinding of a patient. Speak to the physician to determine the reason for the request and enter any available information.

19.4.   Other Steroid Use during PICU Admission

Record any steroids other than hydrocortisone that were used during PICU admission. If any other steroids were used, record the date and time of use, and the number of doses.

20. Economic Variables

Therapy/Interventions: Indicate if the patient required any of the interventions listed, and the total time (in hours) the intervention was used

Services Consulted: Record the number of services consulted as part of the patient's care during PICU admission, and list the specific services that were consulted. Examples include: nursing, respiratory therapy, social work, psychology, physiotherapy.

Caregiver Information: Provide the indicated caregiver information. **Information on where the family/caregiver is staying, and caregiver work status is not typically recorded in the patient's chart. This information will need to be obtained from the caregiver (if your REB would not require separate consent to speak to caregiver) or from the bedside staff while the patient is in hospital.**

PICU Resources:
- Indicate the gross daily cost for a PICU bed at your site.
- Record the number of days the patient was admitted to the PICU, then for each day of admission, record the nurse to patient ratio during PICU admission. If the nurse to patient ratio changed during the day, record the highest ratio (e.g. 1:1 > 1:2) used that day.

21. Protocol Deviation/Violation Report

Any protocol deviation or violation that occurs must be documented on the Protocol Deviation/Violation Report form in the eCRF. There is space to report up to 3 protocol deviations/violations for each patient. If additional space is required, please contact the SCC. See "Protocol Violations and Deviations" in the study SOP for more information on reporting protocol deviations/violations.

22. Serious Adverse Event (SAE) Report

If an SAE occurs, it must be documented on the Serious Adverse Event Reporting Form in the eCRF. See "Serious Adverse Event Reporting" in the study SOP for more information on monitoring and reporting SAEs Space has been provided in the eCRF to report up to three SAEs for a given patient. If additional space is required, please contact the SCC. Once the Reporting Form has been completed, it should be printed, signed by the Site Investigator, and faxed to the SCC. Print a copy of the SAE report by selecting "This entry form with saved record data" from the "Download PDF of" dropdown menu at the top right of the screen. Alternatively, the Site Investigator can use the "E-Signature" function in REDCap to sign the report electronically. The SCC must be notified by phone or email when an SAE Report Form is completed in the eCRF as REDCap does not have an automatic notification function.

23. Co-Enrolment

List (if applicable) any studies the patient was enrolled in during their participation in the STRIPES Pilot Study.

24. Case Report Sign Off

All sections of the eCRF should be saved as "Completed" by the research assistant once the eCRF is complete, and all data has been check for accuracy.

Print a copy of the sign-off page by selecting "This entry form with saved record data" from the "Download PDF of" dropdown menu at the top right of the screen. The person who completed the eCRF and the Site Investigator must sign the printed copy of the sign-off page where indicated. Alternatively, the Site Investigator can use the "E-Signature" function in REDCap to sign the report electronically.

25. Research Blood Sample Results & Group Assignment

Please leave this section blank. The SCC will input these results after all blood samples have been analyzed at study close out.

26. Data Query Process

Date queries will be solved using the Data Resolution Workflow in REDCap. New data queries will be opened by the SCC. You will be notified by the SCC (by phone or email) if there is a new data query that requires your attention. To access the query, choose "Resolve Issues" from the menu on the left-hand side of the screen. A list of all unresolved data queries will appear. Click on the hyperlink in the "Record" column to go to an open query.

A yellow bubble with a red exclamation mark will appear beside the question that the data query pertains to.

Verify the entered data and make changes as required. Select "Save and Continue" at the bottom of the page. Once you have saved the corrected data entry, click on the yellow data query bubble to open the Data Resolution Workflow window. Using the dropdown menu, select the action you took to resolve the data query, enter any comments, and then select "Respond to Query".
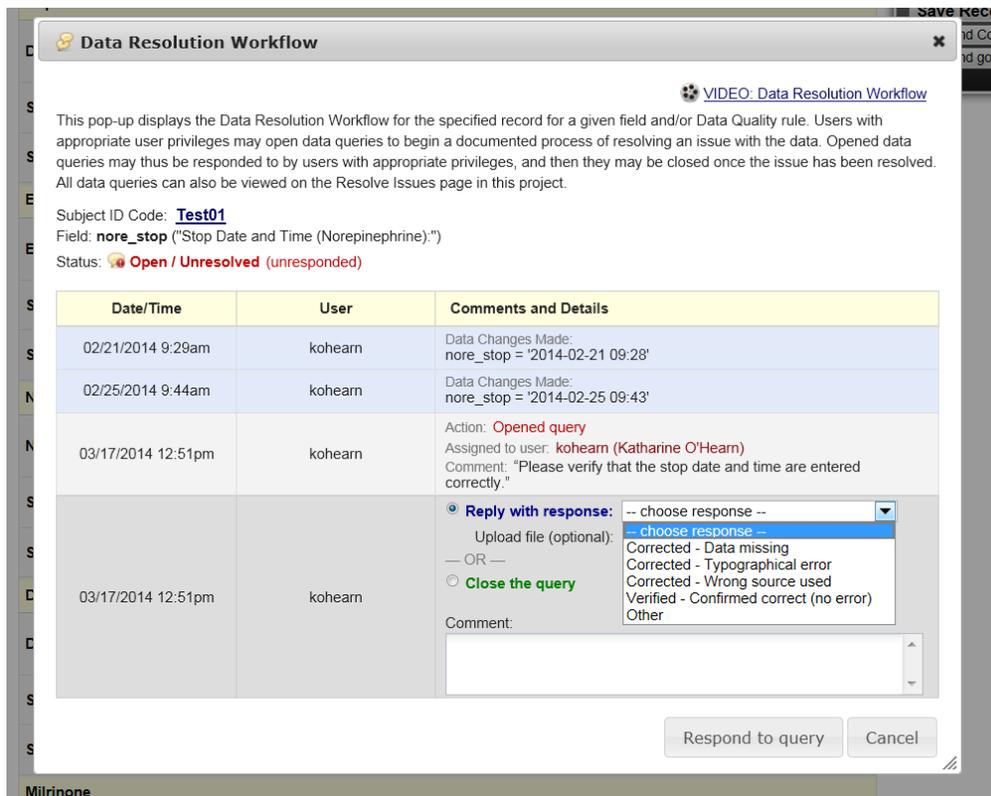
The SCC will then close the query, or may contact you for further clarification. This entire process will be documented in the Data Resolution Workflow window.

27. eCRF Troubleshooting

If you have questions about the eCRF and data collection, please contact the Study Coordinator.

If you have additional research staff who require a username and password to access the study eCRF, please contact the Study Coordinator.

If you have questions about the functionality of REDCap, or are having technical difficulties, please contact the Study Coordinator or the REDCap administrator.

Study Coordinator:	REDCap Administrator:
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