HS FORMS

Changes as of 08-12-2008

Complete this form for:
- Any patient for whom a bag of study fluid was opened even if determined not to be eligible or fluid not given.
Main data source: PCR
Other data resources: Dispatch

ROC Hypertonic Saline Protocol

Patient Enrollment

Version 1.03.00
Date: 01/24/2008

Date *(mm/dd/yyyy)*
[ ] / [ ] / [ ]

Time call received at dispatch*(24hr clock)*
[ ] : [ ] : [ ] *(hh:mm:ss)* ○ **Estimated** ○ **From dispatch**

HS ID:
[ ] - [ ] - [ ]

Site Linking ID *(optional)*
[ ]

Incident Number*(optional)*
[ ]

1. **EMS Agency that provided study intervention:**

Agency Name & Number	Vehicle name
[▼]	[ ]

2. **Study fluid:**
   a. **Bag #:** [ ]
   b. **Was fluid given?**
      ○ No → complete **Alert CTC** form
      ○ Yes
      Amount of study fluid given:
      [ ] (ml) → If < 250ml, complete **Alert CTC** form
      Where was study fluid started?
      ○ Pre-hospital setting
      ○ ED/hospital → complete **Alert CTC** form

3. **Was more than one victim treated with study fluid during this incident?**
   ○ Yes → Number of victims: [ ]
   ○ No

4. **Inclusion criteria** *(Some patients may meet the inclusion criteria for both cohorts)*

TBI Cohort

Yes	No	Blunt head trauma leading to
○	○	Pre-hospital GCS ≤ 8 *(without paralytics)*

Hypovolemic Shock Cohort

Yes	No	Blunt or penetrating trauma leading to ***either***
○	○	Pre-hospital SBP ≤ 70 mmHg
		OR
○	○	Pre-hospital SBP 71 - 90 AND HR ≥ 108

If "No" to all three inclusion criteria above, complete an **Alert CTC** form and indicate the intended cohort:
☐ Intended to enroll in hypotensive cohort
☐ Intended to enroll in TBI cohort

5. **Exclusion criteria:** *(If "Yes" to any exclusion criteria, complete **Alert CTC** form)*

Yes	No	
○	○	Known or suspected pregnancy
○	○	Age ≤ 14 years or weight < 50 kg if age unknown
○	○	Ongoing pre-hospital Cardiopulmonary Resuscitation (CPR)
○	○	Admin of > 2 L crystalloid or any amount of: colloid, blood product, or Mannitol
○	○	Severe hypothermia (suspected T < 28 C)
○	○	Drowning or asphyxia due to hanging
○	○	Burns TBSA > 20%
○	○	Isolated penetrating injury to the head
○	○	Inability to obtain pre-hospital intravenous access
○	○	Time of call received at dispatch to study intervention > 4 hours
○	○	Known prisoner

continue to page 2

Date *(mm/dd/yyyy)*
__ / __ / ____

Time call received at dispatch*(24hr clock)*
__ : __ : __ *(hh:mm:ss)* ○ **Estimated** ○ **From dispatch**

HS ID:
__ - __ - __

Site Linking ID *(optional)*

Incident Number*(optional)*

6. Was this a "modified scene" patient?

○ No → **STOP HERE**
○ Yes → complete items below

Instructions: Complete this section when a patient is admitted to an Emergency Department in anticipation of transportation to a ROC hospital by an air EMS agency. The patient should not be admitted to the hospital nor have any treatments beyond what a typical ALS EMS could provide and typically stay less than 20 minutes.

a. Name of hospital where admitted to the ED:

b. Arrival time at the ED:
__ : __ *(hh:mm)*

c. Treatments while in the ED:

NA/NR	Done	
○	○	IV line *(check all attempted)*
		☐ IV peripheral
		☐ IV central line
○	○	Airway *(check all attempted/used)*
		☐ Oral ET
		☐ Nasal ET
		☐ Cricothyrotomy
		☐ RSI
○	○	Tests
		☐ CXR
		☐ CT scan
		☐ Chest tube
		☐ Blood work results while in ED
○	○	Other → specify: *(100)*

d. Departure time from this ED:
__ : __ *(hh:mm)*

Person responsible for data on this form:

Complete this form for:
-all patients.
Main data source: PCR
Other data resources: Dispatch

ROC Hypertonic Saline Protocol

Pre-hospital Time Record

Version: 1.00.00
Date: 08/17/06

Date *(mm/dd/yyyy)* ___ / ___ / ___

Time call received at dispatch *(24hr clock)* ___ : ___ : ___ *(hh:mm:ss)* ○ **Estimated** ○ **From dispatch**

HS ID: ___ - ___ - ___

Site Linking ID *(optional)* ___

Incident Number *(optional)* ___

-Fill in Event Order, Watch time, and/or Dispatch time for all events that occurred. If an event did not occur, enter "0" for Event Order.
-If no documented time exists (from Watch or Dispatch) fill in event order, leave the time fields blank and check the "No Doc Time" box.
-**Additional Instructions/Documentation**

1st 911 Call received at EMS dispatch:
Call time at Public Safety Answering Point (may be the primary or secondary PSAP) that was responsible for the dispatch of the first responding vehicle. (This first responding vehicle may or may not have the study intervention)

1st vehicle dispatch:
This refers to the time when the first responding vehicle was notified by dispatch.

Time vehicle w/study fluid arrived:
This refers to the first arriving ground or air transport vehicle that administered study fluid.

Time study fluid hung:
This is the time that the study fluid was hung.

Resuscitation terminated due to death:
Enter the time if the patient died OR if resuscitation was halted in the field (DNR status discovered, for example).

1st ED arrival:
The time that the patient arrives at the emergency department or hospital, when the vehicle stops moving.

Item	Event Order 1-6 0=NA	Time of Event						No Doc Time	Computer to generate (you may adjust "Aligned" time)										
		Watch			Dispatch				Aligned Time			Adj	Time Interval			Cumulative Time			
		hh	*mm*	*ss*	*hh*	*mm*	*ss*		*hh*	*mm*	*ss*		*hh*	*mm*	*ss*	*hh*	*mm*	*ss*	
1st 911 call received at dispatch								☐				☐							
Enrolling vehicle dispatch time								☐				☐							
Enrolling vehicle w/study fluid arrived								☐				☐							
Study fluid hung								☐				☐							
Resus. terminated due to death								☐				☐							
1st ED arrival								☐				☐							

Sort Event Order | Align Times | Turn Align Off | Original Order | Reset Form

Person responsible for data on this form

Name: ___

Date *(mm/dd/yyyy)*
/ /

Time call received at dispatch*(24hr clock)*
: : *(hh:mm:ss)* ○ **Estimated** ○ **From dispatch**

HS ID:
- -

Site Linking ID *(optional)*

Incident Number*(optional)*

1. Vital signs:

Initial SBP: mmHg ☐ Not Detectable

Initial RR: breaths/min ☐ NA/NR

Initial GCS (prior to intubation and/or paralytics): E V M

Qualifying GCS (without paralytics): E V M

Qualifying SBP prior to study fluid: mmHg ☐ Not Detectable
* If qualifying SBP 71 - 90, enter qualifying HR bpm

Best field SBP after study fluid: mmHg ○ Not Detectable ○ NA/NR

Highest field HR: bpm

Lowest field SBP: mmHg ☐ Not Detectable

2. Procedures:

Yes No
○ ○ Advanced airway attempted:
If Yes → complete box below

Yes	No	Failed	
○	○	○	LMA
○	○	○	Combitube
○	○	○	King airway
○	○	○	ET Tube
○	○	○	Cricothyrotomy

○ ○ Needle thoracostomy
○ ○ Other, specify below:
(100)

3. Medication given:

○ No → **Skip to item 4**
○ Yes →Yes No
○ ○ Paralytics
○ ○ Narcotics
○ ○ Benzodiazepines
○ ○ Lidocaine
○ ○ Etomidate
○ ○ Other, specify below:
(100)

continue to page 2

Date *(mm/dd/yyyy)*
[ ] / [ ] / [ ]

Time call received at dispatch*(24hr clock)*
[ ] : [ ] : [ ] *(hh:mm:ss)* ○ **Estimated** ○ **From dispatch**

HS ID:
[ ] - [ ] - [ ]

Site Linking ID *(optional)*
[ ]

Incident Number*(optional)*
[ ]

4. Fluids given:

Crystalloid: (NS, LR, Plasmalyte, etc.) [ ] (ml)→If patient was given more than 2L, was it administered before the study fluid?
○ Yes → complete the **Alert CTC** form
○ No

RBC's: [ ] (ml)→Given before study fluid?
○ Yes → complete the **Alert CTC** form
○ No

Mannitol: [ ] (ml)→Given before study fluid?
○ Yes → complete the **Alert CTC** form
○ No

5. Transportation:

Agency name: [ ]
Transport vehicle name: [ ]

[ ]
Transport vehicle name: [ ] → Transport mode: ○ Ground ○ Air

6. Demographics:

a. Age *(estimated from PCR)* [ ]

b. Race/Ethnicity *(check all that apply)*

- ☐ Hispanic or Latino
- ☐ White
- ☐ African-American/Black
- ☐ American-Indian/Alaska Native
- ☐ Asian
- ☐ Native Hawaiian/Pacific Islander
- ☐ Other
- ☐ Unknown/not noted

c. Gender *(check one only)*

- ○ Male
- ○ Female

continue to page 3

Date *(mm/dd/yyyy)*
[ ] / [ ] / [ ]

Time call received at dispatch*(24hr clock)*
[ ] : [ ] : [ ] *(hh:mm:ss)* ○ **Estimated** ○ **From dispatch**

HS ID:
[ ] - [ ] - [ ]

Site Linking ID *(optional)*
[ ]

Incident Number*(optional)*
[ ]

7. Did any adverse events occur during pre-hospital care?

- ○ No
- ○ Yes, explain below and complete the **Alert CTC** form:

[ ] (100)

8. Disposition: *(check one only)*

- ○ Died at scene
- ○ Died en route

} If death in Pre-hospital setting, complete **item 9**

- ○ Admitted to ED→Complete **ED Admit** form

9. Cause of death:

Primary *(check one only)*	**Secondary** *(check one only)*
○ Hypovolemic shock	○ Hypovolemic shock
○ Hypoxia	○ Hypoxia
○ Cardiac dysfunction	○ Cardiac dysfunction
○ TBI	○ TBI
○ Anoxic brain injury	○ Anoxic brain injury
○ Unknown	○ Unknown
○ Other, specify below: [ ] (100)	○ Other, specify below: [ ] (100)

Person responsible for data on this form: [ ]

Date *(mm/dd/yyyy)* ☐☐ / ☐☐ / ☐☐☐☐

Time call received at dispatch*(24hr clock)* ☐☐ : ☐☐ : ☐☐ *(hh:mm:ss)* ○ **Estimated** ○ **From dispatch**

HS ID: ☐☐ - ☐☐☐ - ☐☐☐

Site Linking ID *(optional)* ☐☐☐☐☐☐☐☐

Incident Number*(optional)* ☐☐☐☐☐☐☐☐

1. ED admit information:

ED admittance date: ☐☐ / ☐☐ / ☐☐☐☐ *(mm/dd/yyyy)* **ED admit time:** ☐☐ : ☐☐ *(hh:mm)*

ED name: ▼

ED City: ☐☐☐☐☐☐☐☐

2. Demographics:

a. Birth year: ☐☐☐☐ *(yyyy)*

b. Race: *(check all that apply)*

- ☐ American-Indian/Alaska Native
- ☐ Asian
- ☐ Black/African-American
- ☐ Native Hawaiian/Pacific Islander
- ☐ White
- ☐ Unknown/not noted

c. Ethnicity:

- ○ Hispanic or Latino
- ○ Not Hispanic or Latino
- ○ Unknown/not noted

3. Vital signs within 4 hours of ED admit:

From: ☐☐☐☐☐☐☐☐ **To:** ☐☐☐☐☐☐☐☐

First ED GCS:

E:☐☐ → R size (mm): ☐☐ → Reactive? ○ Yes ○ No
L size (mm): ☐☐ → Reactive? ○ Yes ○ No
V:☐☐ → Intubated? ○ Yes ○ No
M:☐☐ → Chemically paralyzed? ○ Yes ○ No

First ED BP: ☐☐☐ / ☐☐☐ mmHg First ED heart rate: ☐☐☐ bpm

Lowest ED BP: ☐☐☐ / ☐☐☐ mmHg Highest ED heart rate: ☐☐☐ bpm

First Temperature: ☐☐☐ ○ C ○ F ○ NA/NR

→ Source:
- ○ Rectal
- ○ Axillary
- ○ Oral
- ○ Tympanic
- ○ Core

continue to page 2

Date *(mm/dd/yyyy)*
__ / __ / ____

Time call received at dispatch *(24hr clock)*
__ : __ : __ *(hh:mm:ss)* ○ **Estimated** ○ **From dispatch**

HS ID:
__ - ____ - __

Site Linking ID *(optional)*

Incident Number *(optional)*

4. Labs within 4 hours of ED admit:

From: **To:**

Arterial Blood Gases?

○ No
○ Yes →

ABG	% FiO_2 *(decimal)*	pH *(pH units)*	pCO_2 *(mmHg)*	paO_2 *(mmHg)*	SaO_2 *(%)*	Base deficit	Time *(hh:mm, 24hr clock)*
First:							:
Worst: (based on PH)							:

Lactate obtained?

○ No
○ Yes → Indicate unit of measure: ○ mEq/L ○ mmol/L ○ mg/dL
First: ____ Time: __ : __ *(hh:mm)*

Hemoglobin obtained?

○ No
○ Yes → Indicate unit of measure: ○ g/dL ○ g/L
First Hgb: ____ Time: __ : __ *(hh:mm)*
Lowest Hgb: ____ Time: __ : __ *(hh:mm)*

Coag Panel obtained?

○ No
○ Yes → Complete the following:

NA/NR	Done	
○	○	First INR: ____
○	○	First PT: ____ seconds
○	○	First PTT: ____ seconds

Indicate units of measure, then enter value for the following

○ ○ First Platelet : ○ x 10^3/µL ○ x 10^9/L ○ x 10^3/ml³ ____

○ ○ First Fibrinogen: ○ mg/dL ○ g/L ____

5. Did the patient have any ventricular arrhythmias requiring intervention (i.e., shock and/or medication)?

○ Yes
○ No

continue to page 3

Date *(mm/dd/yyyy)*
__ / __ / ____

Time call received at dispatch*(24hr clock)*
__ : __ : __ *(hh:mm:ss)*
○ **Estimated** ○ **From dispatch**

Incident Number*(optional)*
____

HS ID:
__ - ____ - __

Site Linking ID *(optional)*
____

6. Intubation:

- ○ Not intubated
- ○ Arrived intubated
- ○ Intubated in ED
- ○ Surgical airway in ED

7. Angio suite for hemorrhage control?

- ○ No
- ○ Yes → Embolization? ○ Yes ○ No

8. Were any adverse events uncovered during the ED Admit (incomplete study fluid administration, inclusion criteria not met, etc)?

- ○ No
- ○ Yes → Explain: ____ (30) → Complete the **Alert CTC** form.

9. Disposition:

- ○ Operating Room
- ○ ICU
- ○ Intermediate Care Unit
- ○ Regular ward/telemetry
- ○ Discharged
- ○ Left AMA
- ○ Death in ED
- ○ Transfer to another ED → Complete another **ED Admit** form
  - ○ Air
  - ○ Ground

  } Arrival time __ : __ *(24hr clock hh:mm)*

10. Date and time of ED disposition (or death):

Date: __ / __ / ____ *(mm/dd/yyyy)*
Time: __ : __ *(24hr clock hh:mm)*

If death in ED complete **items 11 - 12**, otherwise STOP.

continue to page 4

Date *(mm/dd/yyyy)* ___ / ___ / ___

Time call received at dispatch *(24hr clock)* ___ : ___ : ___ *(hh:mm:ss)*
○ **Estimated** ○ **From dispatch**

Incident Number *(optional)* ___

HS ID: ___ - ___ - ___

Site Linking ID *(optional)* ___

11. For patients who died in the ED, please indicate cause of death here:

Primary *(check one only)*	**Secondary** *(check one only)*
○ Hypovolemic shock	○ Hypovolemic shock
○ Hypoxia	○ Hypoxia
○ Cardiac dysfunction	○ Cardiac dysfunction
○ TBI	○ TBI
○ Anoxic brain injury	○ Anoxic brain injury
○ Unknown	○ Unknown
○ Other, specify below: ___ *(30)*	○ Other, specify below: ___ *(30)*

12. For patients who died in the ED, please indicate if any ED procedures were performed here:

○ No
○ Yes → Complete box below

Procedure	**Procedure numeric code**	**Date** *(mm/dd/yyyy)*
1:	___ → If Other, describe: ___ *(30)*	___ / ___ / ___
2:	___ → If Other, describe: ___ *(30)*	___ / ___ / ___
3:	___ → If Other, describe: ___ *(30)*	___ / ___ / ___
4:	___ → If Other, describe: ___ *(30)*	___ / ___ / ___
5:	___ → If Other, describe: ___ *(30)*	___ / ___ / ___

ED Procedures Key
1. Thoracotomy
2. PA Catheter
3. CVP Catheter
4. Other

Person responsible for data on this form: ___

Complete this form:
-On all patients
Main data source: ED/hospital records

ROC Hypertonic Saline Protocol

Resuscitation / Injury Characteristics

Version 1.04.00
Date: 05/13/2008

Date *(mm/dd/yyyy)* ___ / ___ / ___

Time call received at dispatch *(24hr clock)* ___ : ___ : ___ *(hh:mm:ss)* ○ **Estimated** ○ **From dispatch**

HS ID: ___ - ___ - ___

Site Linking ID *(optional)* ___

Incident Number *(optional)* ___

1. Injury type: *(check all that apply)*

☐ Blunt *(check all that apply)*
- ☐ Fall
- ☐ MVC-motorcyclist
- ☐ MVC-unknown
- ☐ Machinery
- ☐ MVC-cyclist
- ☐ Struck by/against (assault)
- ☐ MVC-occupant
- ☐ MVC-pedestrian
- ☐ Other, describe: ___ *(30)*

☐ Penetrating *(check all that apply)*
- ☐ GSW
- ☐ Stab(knife)
- ☐ Impalement
- ☐ Other, describe: ___ *(30)*

2. Head CT done within 7 days of episode date:

CT	Date	Time	Marshall Head CT Category	NA / NR	Evidence of increased intracranial bleeding?	
	(mm/dd/yyyy)	*(hh:mm)*	*(enter 1-6 code below; if 6, please specify)*		Yes*	No
1:	___ / ___ / ___	___ : ___	___ If Other, specify: ___ *(30)*	☐	—	—
2:	___ / ___ / ___	___ : ___	___ If Other, specify: ___ *(30)*	☐	○	○
3:	___ / ___ / ___	___ : ___	___ If Other, specify: ___ *(30)*	☐	○	○

* If "Yes" to evidence of increased intracranial bleeding, please complete **Alert CTC** form

Marshall Head CT Code:
1. Diffuse Injury I (no visible intracranial pathology seen on CT scan)
2. Diffuse Injury II (cisterns are present, with midline shift 0-5 mm, and/or there is no high or mixed density lesion > 25 cc)
3. Diffuse Injury III (cisterns compressed or absent with midline shift 0-5 mm, no high mixed density lesion > 25 cc)
4. Diffuse Injury IV (midline shift > 5mm, no high or mixed density lesion > 25 cc)
5. Mass Lesion (any lesion surgically evacuated high or mixed density lesion > 25 cc not surgically evacuated)
6. Other

3. Anatomic injuries: *(List 3 worst injuries in each anatomic region; if no injury to an anatomic region, enter "0")*

Injury	Abbreviated Injury Score (7-digit score)		
Head / neck:	1) ___ . ___	2) ___ . ___	3) ___ . ___
Face:	1) ___ . ___	2) ___ . ___	3) ___ . ___
Chest:	1) ___ . ___	2) ___ . ___	3) ___ . ___
Abdomen:	1) ___ . ___	2) ___ . ___	3) ___ . ___
Extremity:	1) ___ . ___	2) ___ . ___	3) ___ . ___
External:	1) ___ . ___	2) ___ . ___	3) ___ . ___

Was AIS data based on autopsy results? ○ Yes ○ No

Which AIS scoring system? ○ 1990 ○ 1998 ○ 2005

continue to page 2

Date *(mm/dd/yyyy)* / /

Time call received at dispatch *(24hr clock)* : : *(hh:mm:ss)* Estimated From dispatch

HS ID: - -

Site Linking ID *(optional)*

Incident Number *(optional)*

4. Injury Severity Scores:

- New Injury Severity Score (NISS)
- Injury Severity Score (ISS)
- Revised Trauma Score (RTS)
- TRISS Prob Outcome (TRISS)

5. Fluids (based on time call received at dispatch):

	0-24 hours	
	From	To
Date mm/dd/yyyy:		
Time (hh:mm):		
Fluids	**Pre-hospital** *(from Pre-hospital form)*	**ED/hospital**
Study fluid (ml):		
Crystalloid (ml):		
Mannitol (ml):		
Other colloid (ml):		
3% saline (ml):		
Allogeneic RBC's (ml):		
FFP (ml):		
Platelets (ml):		
Cryoprecipitate (ml):		
Autologous blood transfusion(ml):		
Intraoperative EBL (ml):		

6. Labs (based on time of ED admit):

a. Labs *(indicate units of measure then enter value OR check NA/NR for not available/not recorded)*

Highest Lactate units: mEq/L mmol/L mg/dL

Hours	Date/Time From	Date/Time To	Value	NA/NR
0-12				
12-24				

continue to page 3

Date *(mm/dd/yyyy)* / /

Time call received at dispatch *(24hr clock)* : : *(hh:mm:ss)* **Estimated** **From dispatch**

HS ID: - -

Site Linking ID *(optional)*

Incident Number *(optional)*

Continuing from page 2 - Item 6

Worst Base Deficit (measured in mmol/L or mEq/L, which are equivalent)

Hours	Date/Time From	Date/Time To	Value	NA/NR
0-12	Date:			
	Time:			
12-24	Date:			
	Time:			

b. Electrolytes: *(Na, Cl and K^+ are measured in either mEq/L or mmol/L, which are equivalent; for not available/not recorded check NA/NR)*

Electrolytes in first 24 hours *(only sodium levels are required every 8 hours)*

Date *(mm/dd/yyyy)*	Time *(hh:mm)*	Na* *(required q8°)*	NA/NR	Cl	NA/NR	K^+	NA/NR
/ /	:						
/ /	:						
/ /	:						
/ /	:						
/ /	:						
/ /	:						
/ /	:						
/ /	:						
/ /	:						
/ /	:						
/ /	:						
/ /	:						
/ /	:						
/ /	:						
/ /	:						

*Any sodium value > 160 will require an **Alert CTC** form to be filled out.

Sort Electrolytes

Highest sodium value from 24-48 hours:

Hours	Date/Time From	Date/Time To	Valu
24-48			

*Any sodium value > 160 will require an **Alert CTC** form to be filled out.

continue to page 4

Date *(mm/dd/yyyy)* ___ / ___ / ___

Time call received at dispatch *(24hr clock)* ___ : ___ : ___ *(hh:mm:ss)* ○ **Estimated** ○ **From dispatch**

HS ID: ___ - ___ - ___

Site Linking ID *(optional)* ___

Incident Number *(optional)* ___

7. Osmolality *(enter 1st/ED value, then enter highest osmolality for subsequent time periods)*

(Osmolality is measured in either mOsm/kg or mmOI/L, which are equivalent; for not available/not recorded check NA/NR. The 1st/ED value should be the first value obtained in the ED, if done. Day 1 equals the date of injury plus one calendar date, etc)

Highest Osm			
Day	Date	Value	NA/NR
1st/ED			☐
Day 1			☐
Day 2			☐
Day 3			☐
Day 4			☐

Person responsible for data on this form: ___

Date *(mm/dd/yyyy)*
/ /

Time call received at dispatch*(24hr clock)*
: : *(hh:mm:ss)* **Estimated** **From dispatch**

HS ID:
- -

Site Linking ID *(optional)*

Incident Number*(optional)*

1. Initial ICU admit

Date: / / *(mm/dd/yyyy)* Time: : *(hh:mm)*

2. Cardiovascular failure (day 0-28):

Day	Date	Heart Rate	MAP	CVP		PRESSORS	Discharged	Readmitted
0		↓	↓	↓	↓	↓		
1		(bpm)	(mmHg)	(mmHg)	NA/NR	Yes No		
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
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28								

continue to page 2

Date *(mm/dd/yyyy)*
/ /

Time call received at dispatch*(24hr clock)*
: : *(hh:mm:ss)* ○ **Estimated** ○ **From dispatch**

HS ID:
- -

Site Linking ID *(optional)*

Incident Number*(optional)*

3. ☐ **Never ventilated** → *Skip to **item 5***

Initial intubation → Date: / / *(mm/dd/yyyy)* Time: : *(hh:mm)*

Day	Date	Ventilated	PaO_2	% FiO_2	PEEP	CXR: bilateral infiltrates?	ALI	ARDS	Vt? If Yes to ALI / ARDS	Extubated	Reintubated
0		Yes No	↓ mmHg	↓ (decimal)	↓ (cmH_20)	Yes No	Yes No	Yes No	↓ (ml/kg/pbw)	☐	☐
1										☐	☐
2		○ ○				○ ○	○ ○	○ ○		☐	☐
3		○ ○				○ ○	○ ○	○ ○		☐	☐
4		○ ○				○ ○	○ ○	○ ○		☐	☐
5		○ ○				○ ○	○ ○	○ ○		☐	☐
6		○ ○				○ ○	○ ○	○ ○		☐	☐
7		○ ○				○ ○	○ ○	○ ○		☐	☐
8		○ ○				○ ○	○ ○	○ ○		☐	☐
9		○ ○				○ ○	○ ○	○ ○		☐	☐
10		○ ○				○ ○	○ ○	○ ○		☐	☐
11		○ ○				○ ○	○ ○	○ ○		☐	☐
12		○ ○				○ ○	○ ○	○ ○		☐	☐
13		○ ○				○ ○	○ ○	○ ○		☐	☐
14		○ ○				○ ○	○ ○	○ ○		☐	☐
15		○ ○				○ ○	○ ○	○ ○		☐	☐
16		○ ○				○ ○	○ ○	○ ○		☐	☐
17		○ ○				○ ○	○ ○	○ ○		☐	☐
18		○ ○				○ ○	○ ○	○ ○		☐	☐
19		○ ○				○ ○	○ ○	○ ○		☐	☐
20		○ ○				○ ○	○ ○	○ ○		☐	☐
21		○ ○				○ ○	○ ○	○ ○		☐	☐
22		○ ○				○ ○	○ ○	○ ○		☐	☐
23		○ ○				○ ○	○ ○	○ ○		☐	☐
24		○ ○				○ ○	○ ○	○ ○		☐	☐
25		○ ○				○ ○	○ ○	○ ○		☐	☐
26		○ ○				○ ○	○ ○	○ ○		☐	☐
27		○ ○				○ ○	○ ○	○ ○		☐	☐
28		○ ○				○ ○	○ ○	○ ○		☐	☐

4. ARDS Qualifying CXR *(Complete only if ARDS checked on **item 3**)*

Chest x-ray date: / / *(mm/dd/yyyy)*

continue to page 3

Date *(mm/dd/yyyy)*
/ /

Time call received at dispatch*(24hr clock)*
: : *(hh:mm:ss)* ○ **Estimated** ○ **From dispatch**

HS ID:
- -

Site Linking ID *(optional)*

Incident Number*(optional)*

5. Other organ failure (day 0-28): *(Data points collected every other day, in ICU only)*

Day	Date	*Indicate unit of measure, then enter value or check NA/NR for not available/not recorded*						GCS			MOD score calculated
		Platelets		**Bilirubin**		**Creatinine**					
0		○ x 10^3/µL ○ x 10^9/L ○ x 10^3/ml^3	NA/NR	○ mg/dL ○ mmol/L	NA/NR	○ mg/dL ○ mmol/L	NA/NR	E	V	M	↓
1											
2			☐		☐		☐				
3			☐		☐		☐				
4			☐		☐		☐				
5			☐		☐		☐				
6			☐		☐		☐				
7			☐		☐		☐				
8			☐		☐		☐				
9			☐		☐		☐				
10			☐		☐		☐				
11			☐		☐		☐				
12			☐		☐		☐				
13			☐		☐		☐				
14			☐		☐		☐				
15			☐		☐		☐				
16			☐		☐		☐				
17			☐		☐		☐				
18			☐		☐		☐				
19			☐		☐		☐				
20			☐		☐		☐				
21			☐		☐		☐				
22			☐		☐		☐				
23			☐		☐		☐				
24			☐		☐		☐				
25			☐		☐		☐				
26			☐		☐		☐				
27			☐		☐		☐				
28			☐		☐		☐				
										Worst MOD score:	

Person responsible for data on this form:

Complete this form for:
- All TBI patients and
- Shock patients with positive head CT findings

Main data source: Hospital records

ROC Hypertonic Saline Protocol

Neurological Function / Management of TBI

Date *(mm/dd/yyyy)* ___ / ___ / ___

Time call received at dispatch *(24hr clock)* ___ : ___ : ___ *(hh:mm:ss)* ○ **Estimated** ○ **From dispatch**

HS ID: ___ - ___ - ___

Site Linking ID *(optional)* ___

Incident Number *(optional)* ___

1. GCS:

Day	Date	Best GCS
1:		
2:		
3:		
4:		
5:		

2. ICP Monitoring?

○ No

○ Yes→ Date placed: ___ / ___ / ___ *(mm/dd/yyyy)*

→ Time placed: ___ : ___ *(hh:mm)*

→ Opening ICP: ___ mmHg → Initial CPP: ___ mmHg

Hours	From	To	Highest ICP (mmHg)	# hrs ICP > 25	# hrs CPP < 60	Total gm/kg Mannitol	NA/NR
0-12:	Date:						↓
	Time:						
12-24:	Date:						☐
	Time:						
24-36:	Date:						☐
	Time:						
36-48:	Date:						☐
	Time:						
48-72:	Date:						☐
	Time:						
72-96:	Date:						☐
	Time:						
96-120:	Date:						☐
	Time:						

continue to page 2

Date *(mm/dd/yyyy)* ___ / ___ / ___

Time call received at dispatch *(24hr clock)* ___ : ___ : ___ *(hh:mm:ss)* ○ **Estimated** ○ **From dispatch**

HS ID: ___ - ___ - ___

Site Linking ID *(optional)* ___

Incident Number *(optional)* ___

3. Other interventions for intracranial hypertension (from the time of 1st ED Admit)?

○ No
○ Yes → Complete box below

Hours	Date/Time		Hyper-ventilation (CO_2 < 30)	Crani-otomy	Ventric-ulostomy
	From	To	Yes No	Yes No	Yes No D/c'd
0-12	Date:		○ ○	○ ○	○ ○ ○
	Time:				
12-24	Date:		○ ○	○ ○	○ ○ ○
	Time:				
24-36	Date:		○ ○	○ ○	○ ○ ○
	Time:				
36-48	Date:		○ ○	○ ○	○ ○ ○
	Time:				
48-72	Date:		○ ○	○ ○	○ ○ ○
	Time:				
72-96	Date:		○ ○	○ ○	○ ○ ○
	Time:				
96-120	Date:		○ ○	○ ○	○ ○ ○
	Time:				

Other 1, specify: ___
Date: ___ / ___ / ___ *(mm/dd/yyyy)* Time: ___ : ___ *(hh:mm)*

Other 2, specify: ___
Date: ___ / ___ / ___ *(mm/dd/yyyy)* Time: ___ : ___ *(hh:mm)*

Other 3, specify: ___
Date: ___ / ___ / ___ *(mm/dd/yyyy)* Time: ___ : ___ *(hh:mm)*

continue to page 3

Date *(mm/dd/yyyy)* ___ / ___ / ___

Time call received at dispatch *(24hr clock)* ___ : ___ : ___ *(hh:mm:ss)* ◯ **Estimated** ◯ **From dispatch**

HS ID: ___ - ___ - ___

Site Linking ID *(optional)* ___

Incident Number *(optional)* ___

4. Any seizures?

◯ No
◯ Yes → Complete box below

Hours	Date/Time			Seizures?	If yes to seizures: Was seizure activity while on anticonvulsant?	Was seizure activity while sodium > 160?
		From	To	Yes No	Yes No	Yes* No
0-12	Date:			◯ ◯	◯ ◯	◯ ◯
	Time:					
12-24	Date:			◯ ◯	◯ ◯	◯ ◯
	Time:					
24-36	Date:			◯ ◯	◯ ◯	◯ ◯
	Time:					
36-48	Date:			◯ ◯	◯ ◯	◯ ◯
	Time:					
48-72	Date:			◯ ◯	◯ ◯	◯ ◯
	Time:					
72-96	Date:			◯ ◯	◯ ◯	◯ ◯
	Time:					
96-120	Date:			◯ ◯	◯ ◯	◯ ◯
	Time:					

* If seizures were associated with sodium > 160 then complete a **CTC Alert** form.

5. Serum Sodium Monitoring During Treatment of Intracranial Hypertension. *(e.g. Mannitol; 3% saline infusion or any other non-study hypertonic saline solution)*

Was there any treatment which required serum sodium monitoring?

◯ No
◯ Yes → complete **a** & **b**

a. Treatments Day 0 - 5

START	Treatments			STOP
Date *(mm/dd/yyyy)* **Time** *(hh:mm)*	3% Sodium	Mannitol	**Other → describe**	**Date** *(mm/dd/yyyy)* **Time** *(hh:mm)*
___ / ___ / ___ ___ : ___	◯	◯	◯ → ___ (20)	___ / ___ / ___ ___ : ___
___ / ___ / ___ ___ : ___	◯	◯	◯ → ___ (20)	___ / ___ / ___ ___ : ___
___ / ___ / ___ ___ : ___	◯	◯	◯ → ___ (20)	___ / ___ / ___ ___ : ___
___ / ___ / ___ ___ : ___	◯	◯	◯ → ___ (20)	___ / ___ / ___ ___ : ___
___ / ___ / ___ ___ : ___	◯	◯	◯ → ___ (20)	___ / ___ / ___ ___ : ___

continue to page 4

Date *(mm/dd/yyyy)* ___ / ___ / ___

Time call received at dispatch *(24hr clock)* ___ : ___ : ___ *(hh:mm:ss)* ○ **Estimated** ○ **From dispatch**

HS ID: ___ - ___ - ___

Site Linking ID *(optional)* ___

Incident Number *(optional)* ___

continuing from page 3 - item 5

b. Sodium Levels Day 0 - 5. Sodium must be monitored every 6 hours during treatment(s) described in item a and once more 6 hours after treatment is discontinued. *(Include sodium levels from the 1st 24 hours only if they are required for a specific treatment in **item 5a**.)*

Date *(mm/dd/yyyy)*	Time *(hh:mm)*	Na*
/ /	:	
/ /	:	
/ /	:	
/ /	:	
/ /	:	
/ /	:	
/ /	:	
/ /	:	
/ /	:	
/ /	:	
/ /	:	
/ /	:	
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/ /	:	
/ /	:	
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/ /	:	
/ /	:	
/ /	:	
/ /	:	

*Any sodium level > 160 will require an **Alert CTC** form to be filled out.

Sort Sodium Measurements

Person responsible for data on this form: ___

Date *(mm/dd/yyyy)* / /

Time call received at dispatch*(24hr clock)* : : *(hh:mm:ss)* **Estimated** **From dispatch**

HS ID: - -

Site Linking ID *(optional)*

Incident Number*(optional)*

1. CVP/PA Catheter used during first 48 hours of resuscitation (from ED Admit):

	From	To
Date:		
Time:		

Yes	No	
○	○	CVP Catheter
○	○	PA Catheter

IF PATIENT DISCHARGED PRIOR TO DAY 3, **STOP HERE**

2. Insulin from day of episode:

Indicate units of measure for glucose: ○ mg/dL ○ mmol/L

Day/Date	Highest Glucose		Insulin Drip?	
	Value	NA/NR	Yes	No
3:		☐	○	○
4:		☐	○	○
5:		☐	○	○

3. Transfusion from day of episode:

Indicate units of measure for HgB: ○ g/dL ○ g/L

Day/Date	Lowest Hgb		Transfusion?	
	Value	NA/NR	Yes	No
3:		☐	○	○
4:		☐	○	○
5:		☐	○	○

4. Sedation from day of episode:

Day/Date	Benzo drip?		Narcotic drip?		Propofol drip?	
	Yes	No	Yes	No	Yes	No
3:	○	○	○	○	○	○
4:	○	○	○	○	○	○
5:	○	○	○	○	○	○

5. Nutrition from day of episode?

Day/Date	Enteral nutrition?		Parenteral nutrition?	
	Yes	No	Yes	No
3:	○	○	○	○
4:	○	○	○	○
5:	○	○	○	○

Date *(mm/dd/yyyy)*
__ / __ / ____

Time call received at dispatch*(24hr clock)*
__ : __ : __ *(hh:mm:ss)* ○ **Estimated** ○ **From dispatch**

HS ID:
__ - ____ - __

Site Linking ID *(optional)*

Incident Number*(optional)*

1. Date admitted to hospital: __ / __ / ____ *(mm/dd/yyyy)*

2. Major procedures:

○ No → **Skip to item 3**
○ Yes →

Procedures	Code	Date (mm/dd/yyyy)
1:		/ /
2:		/ /
3:		/ /
4:		/ /
5:		/ /
6:		/ /
7:		/ /
8:		/ /
9:		/ /
10:		/ /

Procedures key code:

1. Tracheostomy
2. Laparotomy
3. Laparotomy with enteric injury
4. Thoracotomy/sternotomy/VATS
5. Percutaneous drainage of empyema, lung abscess, intra-abdominal abscess
6. Peripheral vascular *(by pass grafting, or major vascular repair)*
7. Open fixation of fracture *(includes fasciotomy for extremity compartment syndrome)*
8. Craniotomy
9. Neck exploration
10. Angiographic control of hemorrhage

continue to page 2

Date *(mm/dd/yyyy)*
__ / __ / ____

Time call received at dispatch*(24hr clock)*
__ : __ : __ *(hh:mm:ss)* ○ **Estimated** ○ **From dispatch**

HS ID:
__ - ____ - __

Site Linking ID *(optional)*

Incident Number*(optional)*

3. Infection?

○ No → **Skip to item 5**
○ Yes →

Infection	Location code	Date (mm/dd/yyyy)
1:		/ /
2:		/ /
3:		/ /
4:		/ /
5:		/ /
6:		/ /
7:		/ /
8:		/ /
9:		/ /
10:		/ /

Infection location key codes to be used in above table:

1. Pneumonia
2. Bloodstream infection
3. UTI
4. Meningitis
5. Cholecystitis
6. Empyema
7. Pseudomembranous colitis
8. Line infection
9. Wound infection
10. Intra-abdominal abscess
11. Osteomyelitis

4. Pneumonia diagnosis method:*(If one of the infections above is pneumonia, indicate diagnosis method. Check one only)*

○ Bronchoalveolar lavage
○ Protected specimen brushing
○ Positive sputum gram stain

continue to page 3

Date *(mm/dd/yyyy)*
__ / __ / ____

Time call received at dispatch*(24hr clock)*
__ : __ : __ *(hh:mm:ss)* ○ **Estimated** ○ **From dispatch**

HS ID:
__ - __ - __

Site Linking ID *(optional)*

Incident Number*(optional)*

5. Non-infectious complication?

○ No → **Skip to item 6**
○ Yes →

Complications	Code	Date (mm/dd/yyyy)
1:		/ /
2:		/ /
3:		/ /
4:		/ /
5:		/ /
6:		/ /
7:		/ /
8:		/ /
9:		/ /
10:		/ /

Complications key code:

1. Fat embolism syndrome
2. Cardiac arrest
3. Myocardial infarction
4. Cerebral infarction
5. Deep venous thrombosis (DVT)
6. Pulmonary embolus
7. Abdominal compartment syndrome
8. Extremity compartment syndrome

6. Date and time of final acute care hospital discharge or death?

Date of discharge or death: __ / __ / ____ *(mm/dd/yyyy)*
Time of discharge or death: __ : __ 24 hr clock *(hh:mm)*

7. Total ICU days:

8. Since original hospital admission, was patient transferred to another acute care hospital for treatment of injuries suffered during original event? *(As opposed to transfer to inpatient rehabilitation or a ventilation weaning facility or a skilled nursing facility etc.)*

○ No
○ Yes →Name and location of discharge hospital

Hospital name:
City:
State/Province:

continue to page 4

Date *(mm/dd/yyyy)*
__ / __ / ____

Time call received at dispatch*(24hr clock)*
__ : __ : __ *(hh:mm:ss)* ○ **Estimated** ○ **From dispatch**

HS ID:
__ - __ - __

Site Linking ID *(optional)*

Incident Number*(optional)*

9. Was TBI outcome interview administered prior to hospital discharge (TBI patients only)?

- ○ Yes
- ○ No → Why not?
  - ○ Patient unavailable
  - ○ Family unavailable
  - ○ LAR unavailable
  - ○ Refused consent

10. Disposition at discharge:*(check one only)*

- ○ Inpatient rehabilitation facility
- ○ Inpatient psychiatric facility
- ○ Skilled nursing facility
- ○ Nursing home
- ○ Home with services
- ○ Home
- ○ Jail
- ○ Against medical advice
- ○ Death → Place of death: *(check one only)*
  - ○ Operating room
  - ○ ICU
  - ○ Intermediate Care Unit
  - ○ Regular ward/telemetry
  - ○ Other: *(30)*

11. Cause of death:

Primary *(check one only)*	**Secondary** *(check one only)*
○ Hypovolemic shock	○ Hypovolemic shock
○ Sepsis	○ Sepsis
○ Hypoxia	○ Hypoxia
○ Cardiac dysfunction	○ Cardiac dysfunction
○ TBI	○ TBI
○ Anoxic brain injury	○ Anoxic brain injury
○ Multiple organ failure	○ Multiple organ failure
○ Pulmonary embolism	○ Pulmonary embolism
○ Unknown	○ Unknown
○ Other, specify below: *(30)*	○ Other, specify below: *(30)*

continue to page 5

Date *(mm/dd/yyyy)*
__ / __ / ____

Time call received at dispatch*(24hr clock)*
__ : __ : __ *(hh:mm:ss)* ○ **Estimated** ○ **From dispatch**

HS ID:
__ - __ - __

Site Linking ID *(optional)*

Incident Number*(optional)*

12. Was care withdrawn prior to death?

○ No
○ Yes →Reason:

Yes	No	
○	○	CNS Issues *(eg. brain death, devastating or non-survivable head injury)*
○	○	Organ failure
○	○	Other, describe: *(30)*

13. Were any adverse events uncovered during the hospitalization? *(e.g. found to be pregnant after hospital admit)*

○ No
○ Yes →Explain: *(30)* → Complete the **Alert CTC** form.

Interim vital status: Complete this if patient still hospitalized at the time of hospital form completion or DSMB vital status sweep.

Patient still hospitalized as of this date: __ / __ / ____ *(mm/dd/yyyy)*

Person responsible for data on this form:

Complete this form for:
-all TBI patients (at discharge, at one month post discharge and at 6 months post-injury)

ROC Hypertonic Saline Protocol

TBI Outcome Interview

Version 1.03.00
Date: 03/25/2008

Date *(mm/dd/yyyy)* ___ / ___ / ___

Time call received at dispatch *(24hr clock)* ___ : ___ : ___ *(hh:mm:ss)* ○ **Estimated** ○ **From dispatch**

HS ID: ___ - ___ - ___

Site Linking ID *(optional)* ___

Incident Number *(optional)* ___

1. Interview

Date: ___ / ___ / ___ *(mm/dd/yyyy)*

Interviewer: ___ *(30)*

Interval post injury: ___

2. Respondent:

○ Patient alone → complete Additional Information **item a**
○ Caregiver alone → complete Additional Information **item b**
○ Patient & Caregiver → complete Additional Information **item a & b**
○ Discharge TBI Outcome Interview information obtained from chart
Explain why then go to **item 3**: ___ *(180)*

Additional Information

a. Was patient able to answer these questions?

	Yes	No
(1)"Can you tell me what you will be asked to do as a participant in this study?"	○	○
(2)"Can you tell me what you can do if you no longer wish to participate in the study?"	○	○

b. Identify caregiver: ○ Relative ○ Friend ○ Professional (RN, employed caregiver)
Number of hours spent with patient per day: ___

GOSE Section

3. Consciousness:

a. Is the head injured person able to obey simple commands or say any words?

(Anyone who shows ability to obey even simple commands, or utter any words or communicate specifically in any other way is no longer considered to be in a vegetative state. Eye movements are not reliable evidence of meaningful responsiveness. If unclear, corroborate with nursing staff.)

○ Yes
○ No

4. Independence in the home:

a. Is the assistance of another person at home essential every day for some activities of daily living?

(For a No, the patient should be able to care for himself at home for 24 hours if necessary. Independence include the ability to plan for and carry out the following activities: bathing, dressing, preparing food, dealing with callers, and handling minor domestic crises. The person should be able to carry out these activities without prompting or reminding and should be capable of being left alone overnight.)

○ Yes → complete **items b & c**
○ No → complete **item c only**

b. Does the patient require frequent help or someone to be around the home most of the time?

(For a No, the patient should be able to care for himself for up to 8 hours a day if necessary.)

○ Yes
○ No

c. Was assistance at home required before the injury?

○ Yes
○ No

continue to page 2

Date *(mm/dd/yyyy)* ___ / ___ / ___

Time call received at dispatch*(24hr clock)* ___ : ___ : ___ *(hh:mm:ss)* ○ **Estimated** ○ **From dispatch**

HS ID: ___ - ___ - ___

Site Linking ID *(optional)* ___

Incident Number*(optional)* ___

5. Independence outside the home

a. Shopping:

(This includes being able to plan what to buy, take care of money independently and behave appropriately in public.)

i. Can the patient shop without assistance?

○ Yes
○ No

ii. Was the patient able to shop without assistance prior to the injury?

○ Yes
○ No

b. Travel:

(This includes either driving or use of public transit. Ability to use a taxi is sufficient, provided the person can call for the taxi and instruct the driver independently.)

i. Is the patient able to travel locally without assistance?

○ Yes
○ No

ii. Was the patient able to travel without assistance prior to the injury?

○ Yes
○ No

c. Work:

(If patients were working before, then their current capacity for work should be at the same level. If they were seeking work before, then the injury should not have adversely affected their chance of obtaining work at the level to which they were eligible. If the patient was a student before the injury, then their capacity for study should not have been adversely affected.)

i. Is the patient working at his/her previous capacity?

○ Yes → complete **item iii** only
○ No → complete **items ii and iii**

ii. How restricted are they?

○ Reduced work capacity
○ Able to work only in a sheltered workshop or non-competitive job
○ Unable to work at all

iii. Prior to injury was the patient?

○ Working full-time, list occupation: ___ *(30)*
○ Working part-time, list occupation: ___ *(30)*
○ Seeking employment
○ Student, level of education: ___ *(30)*
○ Homemaker
○ Retired
○ Unable to work

continue to page 3

Date *(mm/dd/yyyy)* ___ / ___ / ___

Time call received at dispatch*(24hr clock)* ___ : ___ : ___ *(hh:mm:ss)* ○ **Estimated** ○ **From dispatch**

HS ID: ___ - ___ - ___

Site Linking ID *(optional)* ___

Incident Number*(optional)* ___

6. Social & Leisure activities:

(They need not have resumed all their previous leisure activities, but should not be prevented by physical or mental impairment. If they have stopped the majority of activities because of loss of interest or motivation then this is also considered a disability.)

a. Is the patient able to resume regular social and leisure activities outside the home?

- ○ Yes → complete **item c** only
- ○ No → complete **items b and c**

b. What is the extent of restriction on their social and leisure activities?

- ○ Participate a bit less *(at least half as often as before injury)*
- ○ Participate much less *(less than half as often)*
- ○ Unable to participate *(rarely, if ever, take apart)*

c. Did the patient engage in regular social and leisure activities outside the home before the injury?

- ○ Yes
- ○ No

7. Family & Friendships:

(Typical post-traumatic personality changes: quick temper, irritability, anxiety, insensitivity to others, mood swings, depression, and unreasonable childish behavior.)

a. Have there been psychological problems which have resulted in ongoing family disruption or disruption to friendships?

- ○ Yes → complete **items b and c**
- ○ No → complete **item c** only

b. What has been the extent of the disruption or strain?

- ○ Occasional *(less than weekly)*
- ○ Frequent *(once a week or more, but tolerable)*
- ○ Constant *(daily and intolerable)*

c. Were there problems with family or friends before the injury?

(If there were some problems, but the problems have become markedly worse since the injury then the answer should be NO)

- ○ Yes
- ○ No

8. Return to normal life:

(Other typical problems reported after head injury include: headaches, dizziness, tiredness, sensitivity to noise/light, slowness, memory failures, and concentration problems.)

a. Are there any other current problems relating to the injury that affect daily life?

- ○ Yes
- ○ No

b. Were there similar problems present before the injury?

- ○ Yes
- ○ No

continue to page 4

Date *(mm/dd/yyyy)* ___ / ___ / ___

Time call received at dispatch *(24hr clock)* ___ : ___ : ___ *(hh:mm:ss)* ○ **Estimated** ○ **From dispatch**

HS ID: ___ - ___ - ___

Site Linking ID *(optional)* ___

Incident Number *(optional)* ___

9. What do you feel has had the greatest impact on outcome following this injury?

- ○ Effects of the head injury
- ○ Effects of the injury to another part of the body
- ○ A combination of these

DRS Section

10. Level of consciousness:

a. Does the patient open eyes?

- ○ **Spontaneous** *(eyes open with sleep/wake rhythms indicating active arousal mechanisms, does not assume awareness.)*
- ○ **To speech** *(a response to any verbal approach, whether spoken or shouted, not necessarily the command to open the eyes. Also, response to touch, mild pressure.)*
- ○ **To pain** *(tested by a painful stimulus.)*
- ○ **None** *(no eye opening even to painful stimulation.)*

b. Communication ability:

- ○ **Oriented** *(implies awareness of self and the environment. Patient able to tell you a) who he is; b) where he is; c) why he is there; d) year; e) season; f) month; g) day; h) time of day.)*
- ○ **Confused but conversant** *(attention can be held and patient responds to questions but responses are delayed and/or indicate varying degrees of disorientation and confusion.)*
- ○ **Inappropriate** *(intelligible articulation but speech is used only in an exclamatory or random way (such as shouting and swearing); no sustained communication exchange is possible.)*
- ○ **Incomprehensible** *(moaning, groaning or sounds without recognizable words, no consistent communication signs.)*
- ○ **None** *(no sounds or communications signs from patient.)*

c. What is the patient's best motor response?

- ○ **Obeys commands** *(obeying command to move finger on best side. If no response or not suitable try another command such as "move lips", "blink eyes", etc. Do not include grasp or other reflex responses.)*
- ○ **Localizes to pain** *(a painful stimulus at more than one site causes limb to move (even slightly) in an attempt to remove it. It is a deliberate motor act to move away from or remove the source of noxious stimulation. If there is doubt as to whether withdrawal or localization has occurred after 3 or 4 painful stimulation, rate as localization.)*
- ○ **Withdraws from pain** *(any generalized movement away from a noxious stimulus that is more than a simple reflex response.)*
- ○ **Flexor posturing** *(painful stimulation results in either flexion at the elbow, rapid withdrawal with abduction of the shoulder or a slow withdrawal with adduction of the shoulder. If there is confusion between flexing and withdrawing, then use pinprick on hands.)*
- ○ **Extensor posturing** *(painful stimulation results in extension of the limb.)*
- ○ **None** *(no response can be elicited. Usually associated with hypotonia. Exclude spinal transection as an explanation of lack of response; be satisfied that an adequate stimulus has been applied.)*

continue to page 5

Date *(mm/dd/yyyy)* ___ / ___ / ___

Time call received at dispatch *(24hr clock)* ___ : ___ : ___ *(hh:mm:ss)* ○ **Estimated** ○ **From dispatch**

HS ID: ___ - ___ - ___

Site Linking ID *(optional)* ___

Incident Number *(optional)* ___

continued from page 4 Item 11

11. Cognitive ability to feed, toilet & groom:

a. Does the patient have the cognitive ability to feed himself?

- ○ **Complete** *(continuously shows awareness that he knows how to feed and can convey unambiguous information that he knows when this activity should occur.)*
- ○ **Partial** *(intermittently shows awareness that he knows how to feed and/or can intermittently convey reasonably clearly information that he knows when the activity should occur.)*
- ○ **Minimal** *(shows questionable or infrequent awareness that he knows in a primitive way how to feed and/or shows infrequently by certain signs, sounds, or activities that he is vaguely aware when the activity should occur.)*
- ○ **None** *(shows virtually no awareness at any time that he knows how to feed and cannot convey information by signs, sounds, or activity that he knows when the activity should occur.)*

b. Does the patient have the cognitive ability to use the toilet?

- ○ **Complete** *(continuously show awareness that he knows how to toilet and can convey unambigous information that he knows when this activity should occur.)*
- ○ **Partial** *(intermittently shows awareness that he knows how to toilet and/or can intermittently convey reasonably clearly information that he knows when the activity should occur.)*
- ○ **Minimal** *(shows questionable or infrequent awareness that he knows in a primitive way how to toilet and/or shows infrequently by certain signs, sounds, or activities that he is vaguely aware when the activity should occur.)*
- ○ **None** *(shows virtually no awareness at any time that he knows how to toilet and cannot convey information by signs, sounds, or activity that he knows when the activity should occur.)*

c. Does the patient have the cognitive ability to groom and dress?

- ○ **Complete** *(continuously shows awareness that he knows how to groom self and can convey unambiguous information that he knows when this activity should occur.)*
- ○ **Partial** *(intermittently shows awareness that he knows how to groom self and/or can intermittently convey reasonably clearly information that he know when the activity should occur.)*
- ○ **Minimal** *(shows questionable or infrequent awareness that he knows in a primitive way how to groom self and/or shows infrequently by certain signs, sounds, or activities that he is vaguely aware when the activity should occur.)*
- ○ **None** *(shows virtually no awareness at any time that he knows how to groom self and cannot convey information by signs, sounds, or activity that he knows when the activity should occur.)*

12. How would you describe the patient current level of functioning (physical, mental, emotional, or social)?

- ○ **Completely independent** *(able to live as he wishes, requiring no restriction due to physical, mental, emotional or social problems.)*
- ○ **Independent in a special environment** *(capable of functioning independently when needed requirements are met (mechanical aids such as crutches, cane, memory book etc).)*
- ○ **Mildly dependent-limited assistance** *(able to care for most of own needs but requires limited assistance due to physical, cognitive and/or emotional problems (e.g., needs non-resident helper).)*
- ○ **Moderately dependent-moderate assist (person in home)** *(able to care for self partially but needs another person at all times.)*
- ○ **Markedly dependent-assist all major activities all times** *(needs help with all major activities and the assistance of another person at all times.)*
- ○ **Totally dependent-24 hour nursing care** *(not able to assist in own care and requires 24-hour nursing care.)*

Person responsible for data on this form: ___

Complete this form for:
-each potential Adverse Situation where implementation of study protocol resulted in a potential safety issue to the patient, EMS staff, or bystander.
-public objection to the ROC Hypertonic Saline study
-all Adverse Events, protocol violations/deviations/unusual circumstances
Report this information to the CTC within 1 business day of discovery

ROC Hypertonic Saline Protocol

Alert CTC

Version 1.06.00
Date: 08/12/2008

Date *(mm/dd/yyyy)* ___ / ___ / ___

Time call received at dispatch *(24hr clock)* ___ : ___ : ___ *(hh:mm:ss)* ○ **Estimated** ○ **From dispatch**

HS ID: ___ - ___ - ___

Site Linking ID *(optional)* ___

Incident Number *(optional)* ___

0. Is this issue associated with an episode:

○ **No**
○ **Yes → Episode Id:** ___

1. Date reported to CTC: *(earliest date reported, whether by phone or online form)*

___ / ___ / ___ *(mm/dd/yyyy)*

2. Date of situation:

___ / ___ / ___ *(mm/dd/yyyy)*

3. Type of situation:

a. Potential Safety Issues Related to Study Protocol

- ○ Hypertonic Saline protocol caused delay/interruption of treatment
- ○ Public formal objection to ROC Hypertonic Saline Study
- ○ Other potential safety issue

b. Potential Protocol Violations / Deviations

- ○ < 250 ml study fluid given
- ○ Study fluid given by route other than IV
- ○ Sodium monitoring requirements deviation
- ○ Exclusion criteria present
- ○ Other potential protocol violation/protocol deviation
- ○ Case entered 30 days after episode date
- ○ Study fluid given in ED/Hospital setting
- ○ Study fluid not given
- ○ Therapy unblinded
- ○ Inclusion criteria not met
- ○ Found pregnant after ED/hospital admit

Additional Information

Check all that apply for the violation / deviation you have selected.

- ☐ Inability to obtain pre-hospital intravenous access
- ☐ Obviously pregnant
- ☐ Known prisoner
- ☐ Trauma due to hanging
- ☐ Burns TBSA > 20%
- ☐ Ongoing CPR in field prior to study fluid
- ☐ Pre-hospital SBP > 90
- ☐ Pre-hospital GCS ≥ 9
- ☐ Time of call received at dispatch to study intervention > four hours
- ☐ Age obviously ≤ 14 years or weight < 50 kg
- ☐ Severe hypothermia (suspected T < 28 C)
- ☐ Trauma due to drowning
- ☐ Isolated penetrating injury to head
- ☐ Admin of > 2 L crystalloid or any amount of: colloid, blood product, or Mannitol
- ☐ Pre-hospital SBP 71-90 AND HR < 108
- ☐ Other *(explain in **item 4**)*

continue to page 2

Date *(mm/dd/yyyy)*
/ /

Time call received at dispatch *(24hr clock)*
: : *(hh:mm:ss)* **Estimated** **From dispatch**

HS ID:
- -

Site Linking ID *(optional)*

Incident Number *(optional)*

*continued from **item 3***

c. Potential Adverse Events

- Anaphylaxis
- Seizure activity associated with hypernatremia
- Hypernatremia (Na > 160 mg/L)
  Did this require therapeutic intervention? Yes No
  Time of measurement :
- Evidence of increased intracranial hemorrhage on head CT *(as compared to baseline head CT)*
- Any death not explained by injury severity
- Irritation at the infusion site
- Minor allergic reaction, skin rash with no hemodynamic effects
- Other adverse event related to study fluid administration *(explain in **item 4**)*

Additional information

Answer the following questions if any of the Potential Adverse Events is marked:

Life threatening?	Serious?	Related to intervention?	Expected?
Yes	Yes	Yes	Yes
No	No	No	No
Maybe/Possibly	Maybe/Possibly	Maybe/Possibly	Maybe/Possibly

d. Other Unusual Circumstances

- Missing fluid bags
- Damaged fluid bags

Affected Bags: 1) 2) 3) 4)

- Other unusual circumstances

4. Explain circumstances:

(Briefly explain the circumstances surrounding any issues identified above)

*(**480 of 480** characters remaining)*

Person responsible for data on this form:

Date *(mm/dd/yyyy)*
[ ] / [ ] / [ ]

Time call received at dispatch *(24hr clock)*
[ ] : [ ] : [ ] *(hh:mm:ss)* ○ **Estimated** ○ **From dispatch**

HS ID:
[ ] - [ ] - [ ]

Site Linking ID *(optional)*
[ ]

Incident Number *(optional)*
[ ]

1. Was patient and / or family and / or LAR notified that patient was in study?

○ Yes → Who was notified?
- ☐ Family → Date: [ ] / [ ] / [ ] (mm/dd/yyyy)
- ☐ Patient → Date: [ ] / [ ] / [ ] *(mm/dd/yyyy)*
- ☐ LAR → Date: [ ] / [ ] / [ ] *(mm/dd/yyyy)*

○ No → Why not?
[ ] (200)

2. Did patient and / or family and / or LAR consent to review records?

○ Yes → Who gave consent?
- ☐ Family → Date: [ ] / [ ] / [ ] *(mm/dd/yyyy)*
- ☐ Patient → Date: [ ] / [ ] / [ ] *(mm/dd/yyyy)*
- ☐ LAR → Date: [ ] / [ ] / [ ] (mm/dd/yyyy)

○ No → Why not? *(select 1 only)*
- ☐ Expired
- ☐ Patient/family/LAR refused consent → Explain:
  [ ] (200)
- ☐ Other → Document and explain attempts to obtain consent in **item 4**

3. Did patient and / or family and / or LAR consent to a 1 and 6 month follow-up call?

○ Yes → Who gave consent?
- ☐ Family → Date: [ ] / [ ] / [ ] *(mm/dd/yyyy)*
- ☐ Patient → Date: [ ] / [ ] / [ ] *(mm/dd/yyyy)*
- ☐ LAR → Date: [ ] / [ ] / [ ] *(mm/dd/yyyy)*

○ No → Why not? *(select 1 only)*
- ☐ Expired
- ☐ Patient/family/LAR refused consent → Explain:
  [ ] (200)
- ☐ Other → Document and explain attempts to obtain consent in **item 4**

continue to page 2

Date *(mm/dd/yyyy)*
/ /

Time call received at dispatch*(24hr clock)*
: : *(hh:mm:ss)* **Estimated** **From dispatch**

HS ID:
- -

Site Linking ID *(optional)*

Incident Number*(optional)*

4. Attempts to contact patient or patient representative:

Date *(mm/dd/yyyy)*	**Type of attempt:** *(Phone, Clinic visit, Letter, Certified letter, In person, Email & Other)*	**Results/notes**
/ /	If Other, specify: *(30)*	*(200)*
/ /	If Other, specify: *(30)*	*(200)*
/ /	If Other, specify: *(30)*	*(200)*
/ /	If Other, specify: *(30)*	*(200)*
/ /	If Other, specify: *(30)*	*(200)*
/ /	If Other, specify: *(30)*	*(200)*
/ /	If Other, specify: *(30)*	*(200)*
/ /	If Other, specify: *(30)*	*(200)*

Person responsible for data on this form:

Complete this form:
- for all patients discharged alive prior to day 28. (for SHOCK patients call on day 28 from the episode date; for TBI patients call 1 month from hospital discharge date.)

ROC Hypertonic Saline Protocol

First Follow-up

Version 1.02.00
Date: 05/06/2008

Date *(mm/dd/yyyy)* ___ / ___ / ___

Time call received at dispatch*(24hr clock)* ___ : ___ : ___ *(hh:mm:ss)* ○ **Estimated** ○ **From dispatch**

HS ID: ___ - ___ - ___

Site Linking ID *(optional)* ___

Incident Number*(optional)* ___

1. Was the patient (or patient representative) successfully contacted?

○ No →Skip to **item 5** and document attempts to contact patient on **item 6**

○ Yes →Date: ___ / ___ / ___ *(mm/dd/yyyy)*

Where contacted? ○ Home ○ SNF ○ Rehab ○ Jail ○ Clinic

○ Other: ___ *(30)*

2. Was the patient difficult to contact?

○ No

○ Yes → Administer the **TBI Outcome Interview form** (for TBI patients only)

3. Follow-up conducted with whom?

○ Patient

○ Family

○ Other: ___ (30)

4. Was the patient re-hospitalized after discharge?

○ No

○ Unknown

○ Yes→ Length of stay: ___ (days)

→ Reason: ___ (200)

5. Was vital status ascertained?

○ No

○ Yes → complete **items a** & **b** below.

a. Vital status:

○ Alive → Last date known alive: ___ / ___ / ___ *(mm/dd/yyyy)*

○ Dead → Date of death: ___ / ___ / ___ *(mm/dd/yyyy)*

If day of death is not available: ___ / ___ *(mm/yyyy)*

Any available information on cause of death?

○ No

○ Yes, specify → ___ *(100)*

b. How was vital status ascertained?

○ Patient/family

○ Hospital records

○ Clinic notes

○ Obituary/Public records

○ Certified letter signature

○ Other: ___ *(30)*

continue to page 2

Date *(mm/dd/yyyy)*
/ /

Time call received at dispatch*(24hr clock)*
: : *(hh:mm:ss)* ○ **Estimated** ○ **From dispatch**

HS ID:
- -

Site Linking ID *(optional)*

Incident Number*(optional)*

6. Attempts to contact patient or patient representative:

Date *(mm/dd/yyyy)*	**Type of attempt:** *(Phone, Clinic visit, Letter, Certified letter, In person, Email & Other)*	**Results/notes**
/ /	If Other, specify: *(30)*	*(200)*
/ /	If Other, specify: *(30)*	*(200)*
/ /	If Other, specify: *(30)*	*(200)*
/ /	If Other, specify: *(30)*	*(200)*
/ /	If Other, specify: *(30)*	*(200)*
/ /	If Other, specify: *(30)*	*(200)*
/ /	If Other, specify: *(30)*	*(200)*
/ /	If Other, specify: *(30)*	*(200)*
/ /	If Other, specify: *(30)*	*(200)*

Person responsible for data on this form:

Complete this form for:
- TBI patients discharged alive and alive at "First Follow-up"
- contact 6 months from episode date.

ROC Hypertonic Saline Protocol

Follow-up (6 month)

Version 1.02.00
Date: 05/06/2008

Date *(mm/dd/yyyy)* ___ / ___ / ___

Time call received at dispatch *(24hr clock)* ___ : ___ : ___ *(hh:mm:ss)* ◯ **Estimated** ◯ **From dispatch**

HS ID: ___ - ___ - ___

Site Linking ID *(optional)* ___

Incident Number *(optional)* ___

1. Was the patient (or patient representative) successfully contacted?

◯ No → Complete **item 4** and document attempts to contact patient
◯ Yes → Date: ___ / ___ / ___ *(mm/dd/yyyy)*

2. Follow-up conducted with whom?

◯ Patient
◯ Family
◯ Other: ___ (30)

3. Vital status:

◯ Alive → Last date known alive: ___ / ___ / ___ *(mm/dd/yyyy)* → Complete the **TBI Outcome Interview** form
◯ Dead → Date of death: ___ / ___ / ___ *(mm/dd/yyyy)*
If day of death is not available: ___ / ___ *(mm/yyyy)*
Any available information on cause of death?
◯ No
◯ Yes, specify → ___ (100)

4. Attempts to contact patient or patient representative:

Date *(mm/dd/yyyy)*	**Type of attempt:** *(Phone, Clinic visit, Letter, Certified letter, In person, Email & Other)*	**Results/notes**
___ / ___ / ___	If Other, specify: ___ (30)	___ (200)
___ / ___ / ___	If Other, specify: ___ (30)	___ (200)
___ / ___ / ___	If Other, specify: ___ (30)	___ (200)
___ / ___ / ___	If Other, specify: ___ (30)	___ (200)

Person responsible for data on this form: ___