

RESTORE: Form 1: Inclusion/Exclusion Criteria fm01

Form 1: Inclusion/Exclusion Criteria

Note: All dates have been reformulated to be days since study day 0

1.	Screening Date	<input type="text" value="v"/> / <input type="text" value="v"/> / <input type="text" value="v"/>	scrn_dayssince0
Section 6: Inclusion Criteria			
2.	≥ 2 weeks of age and ≥ 42 weeks post menstrual age	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	age2wk
3.	< 18 years of age (has not yet had 18 th birthday)	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	age18yr
4.	Intubated and mechanically ventilated	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	mechvent
5.	Acute lung disease - <u>primary reason</u> for intubation presumed to be airways and/or parenchymal lung disease	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	acutelung
Section 7: Exclusion Criteria			
6.	Expected to be extubated in the next 24 hours	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	extub24
7.	Cyanotic heart disease with unrepaired or palliated right to left intracardiac shunt	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	cyanotic
8.	History of single ventricle at any stage of repair	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	singlevent
9.	Congenital diaphragmatic hernia or congenital/acquired diaphragm paralysis	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	hernia
10.	Primary pulmonary hypertension	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	pph
11.	Critical airway (e.g., post laryngotracheal reconstruction)	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	critair
12.	Anatomical obstruction of the lower airway (e.g., mediastinal mass)	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	obstruct
13.	Ventilator dependent (including noninvasive) at baseline (chronic assisted ventilation)	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	ventdept
14.	Neuromuscular respiratory failure	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	neuromus

15.	Spinal cord injury (SCI) above the lumbar region	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	spinal	
16.	Pain managed by patient controlled analgesia (PCA) or epidural catheter	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	pca	
17.	Patient transferred from an outside ICU where sedatives had already been administered for > 24 hours	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	prevsed	
18.	Family/medical team have decided not to provide full support (patient treatment considered futile or patient is "Do Not Resuscitate")	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	dnr	
19.	Enrolled previously in <i>RESTORE</i>	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	restore	
20.	Enrolled in any other critical care interventional clinical trial concurrently or within the last 30 days	<input type="radio"/> Yes (1) If Yes, please specify the other trial: <input type="radio"/> No (0)	trial	Note: Removed (potentially identifying information) trialname
21.	Known allergy to any of the study medications (morphine and midazolam)	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	allergy	
22.	Patient pregnant	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	pregnant	Note: Missing for early screened patients; added after trial began (7/4/2010 protocol)
Section 8: 7cbZfa 9][[V]]mGHU g				
23.	Is the patient eligible? If the patient is not eligible, STOP. End of data entry for ineligible patient.	<input type="radio"/> Yes (1) If Yes, did the parent/guardian provide consent? consent <input type="radio"/> Yes, consent date and time: (1) <input type="text" value=""/> / <input type="text" value=""/> / <input type="text" value=""/> <input type="text" value=""/> : <input type="text" value=""/> 24-hour clock <input type="radio"/> No (0)	eligible	consent_dayssince day0 Note: 2,459 patients were consented. Full consent for the protocol and data collection was withdrawn by parents for 10 of these patients. Therefore, data from 2,449 patients are included in the other data sets.
		<input type="radio"/> No (0) If consent was not provided, complete "Form 2n: Eligible But Not Enrolled."		

RESTORE: Form 2: Demographic and Medical History Information fm02

Section: Demographic Information

Note: All dates have been reformulated to be days since study day 0

1.	Date of birth	▼ / ▼ / ▼	dob	Note: Removed to deidentify data
2.	Gender	<input type="radio"/> Male (0) <input checked="" type="radio"/> Female (1)	female	
3.	Race	<input type="radio"/> White (1) <input type="radio"/> Black/African American (2) <input type="radio"/> Asian (3) <input type="radio"/> Native Hawaiian or Other Pacific Islander (4) <input type="radio"/> American Indian or Alaskan Native (5) <input type="radio"/> Multiracial/More than one race (6) <input type="radio"/> Declined (7) <input type="radio"/> Unknown/Unavailable (88)	race	Note: Recategorized due to low counts. All responses of (7) and (88) were collapsed to (7)
4.	Ethnicity	<input type="radio"/> Hispanic or Latino (1) <input type="radio"/> Not Hispanic or Latino (2) <input type="radio"/> Declined (3) <input type="radio"/> Unknown/Unavailable (88)	ethnic	Note: Recategorized due to low counts. All responses of (3) and (88) were collapsed to (3)
5.	Baseline (prior to current illness) PCPC	▼ Pulldown list 1	basepcpc	Note: Recategorized due to low counts (see pulldown list 1)
6.	Baseline (prior to current illness) POPC	▼ Pulldown list 2	basepopc	Note: Recategorized due to low counts (see pulldown list 2)
7.	At baseline, was the patient able to verbally communicate his/her level of comfort?	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	verbal	

Section: Admission and Intubation/Ventilation Information

8.	Date of hospital admission	▼ / ▼ / ▼	hospadm_dayssince day0	Note: Changed to days since study day 0
9.	Date and time of PICU admission	▼ / ▼ / ▼ ▼ : ▼ 24-hour clock	picuadm_dayssince day0	Note: Changed to days since study day 0
10.	Weight (at PICU admission)	wt kg	Added Height (at PICU admission) in cm: ht ; BMI in kg/m ² : bmi	
11.	Date and time of intubation Note if patient was a transfer patient. If patient is chronically trached, select N/A and leave date/time blank.	Date and time: ▼ / ▼ / ▼ ▼ : ▼ 24-hour clock <input type="radio"/> Transfer patient (1) <input type="radio"/> N/A Chronic Tracheostomy (1)	intub_dayssince day0 transfer chrontrach	Note: Changed to days since study day 0
12.	Date and time of initiation of assisted breathing	▼ / ▼ / ▼	astbrst_dayssince day0	Note: Changed to days since study day 0

	(including mechanical ventilation, BiPAP, Humidified High Flow Nasal Cannula (HHFNC \geq 5 L/min of Oxygen flow), or CPAP \geq 5 cm H ₂ O)	<input type="text"/> : <input type="text"/> 24-hour clock
13.	Start date and time of Study Day 0	<input type="text"/> / <input type="text"/> / <input type="text"/> studyday0 <input type="text"/> : <input type="text"/> 24-hour clock Note: All dates are relative to this point. Marked as 0 for all individuals

Section: Current Medical History

14.	<u>Primary</u> reason for intubation and mechanical ventilation	<input type="radio"/> Bronchiolitis (1) <input type="radio"/> Asthma or reactive airway disease (2) <input type="radio"/> Laryngotracheobronchitis (croup/tracheitis) (3) primary <input type="radio"/> Pertussis (4) <input type="radio"/> Pneumonia (any organism) (5) <input type="radio"/> Aspiration pneumonia (6) <input type="radio"/> Thoracic trauma: pulmonary contusion or inhalation burns (7) <input type="radio"/> Pneumothorax - non trauma (8) <input type="radio"/> Chronic lung disease: cystic fibrosis or BPD (9) <input type="radio"/> Pulmonary hypertension (not primary) (10) <input type="radio"/> Acute chest syndrome/sickle cell disease (11) <input type="radio"/> Pulmonary edema (12) <input type="radio"/> Pulmonary hemorrhage (13) <input type="radio"/> Acute respiratory failure post BMT (14) <input type="radio"/> Acute respiratory failure related to sepsis (15) <input type="radio"/> Acute respiratory failure related to multiple blood transfusions (16) <input type="radio"/> Other, (00) primaryoth specify: Removed to deidentify data	Note: Recategorized due to low counts. All responses of (8), (10), (16), and (99) were collapsed to (99)
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Section: Acute Lung Injury/Acute Respiratory Distress Syndrome

15.	Was a chest x-ray obtained on the day of intubation? (if chronically trached, on day of mechanical ventilation)	<input type="radio"/> Yes (1) intubxray If Yes, does this patient have acute onset bilateral infiltrates/opacities on x-ray? intubbilat <input type="radio"/> Yes (1) <input type="radio"/> No (0) <input type="radio"/> No (0)
16.	Was an arterial blood gas obtained on Study Day 0 after intubation? (if chronically trached, on day of mechanical ventilation)	<input type="radio"/> Yes (1) intubartblood If Yes, provide blood gas values that yield lowest PF ratio and the mean airway pressure at that PF ratio: PaO ₂ : intubpfpao2

	<p>FiO₂: intubpffio2</p> <p>Mean airway pressure: intubpfmap</p> <p><input type="radio"/> No (0)</p> <p>If No, provide values that yield lowest SF ratio and the mean airway pressure at that SF ratio:</p> <p>SpO₂: intubsfspo2</p> <p>FiO₂: intubsfio2</p> <p>Mean airway pressure: intubsfmap</p>
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17.	Is this patient showing evidence of left atrial (LA) hypertension (e.g., ECHO+)?	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	intublaht
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Section: Past Medical History

18.	Past medical history (check all that apply)	<input type="checkbox"/> Prematurity (< 36 weeks post-menstrual age) pastmhx_premature <input type="checkbox"/> Asthma (prescribed bronchodilators or steroids) pastmhx_asthma <input type="checkbox"/> Bronchopulmonary dysplasia pastmhx_bpd <input type="checkbox"/> Cystic fibrosis pastmhx_cf <input type="checkbox"/> Insulin-dependent diabetes pastmhx_insulindiab Note: Removed due to low counts <input type="checkbox"/> Immunodeficiency (acquired or congenital) pastmhx_immunodef <input type="checkbox"/> Neurologic/neuromuscular disorder which places patient at risk for aspiration pastmhx_aspiration <input type="checkbox"/> Seizure disorder (prescribed anticonvulsant medication) pastmhx_seizures <input type="checkbox"/> Post bone marrow transplant or undergoing active chemotherapy for any oncologic process pastmhx_bmtchemo <input type="checkbox"/> Sickle cell disease pastmhx_sicklecell Note: Individuals with insulin-dependent diabetes and no other medical history were marked as "None of the above" <input type="checkbox"/> None of the above pastmhx_nomhx
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Section: Follow-up Study

19.	Did the parent/guardian provide consent for follow-up?	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	consentfu2 Note: Removed for duplicity (see Form 8, Question 12)
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Section: Ancillary Studies

20.	Did the parent/guardian provide consent for the BALI study?	<input type="radio"/> No (0) <input type="radio"/> Yes (1)	balicons Note: Removed; To be included in separate data submission
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		If Yes, BALI Enrollment Number: <input data-bbox="709 94 919 138" type="text" value="invalid"/> <input type="radio"/> Not applicable (2)	Note: Removed to deidentify data
21.	Did the parent/guardian provide consent for the PISA study?	<input type="radio"/> No (0) <input type="radio"/> Yes (1) kincons <input type="radio"/> Not applicable (2)	Note: Removed; To be included in separate data submission

RESTORE: Form 3: Prism III-12 fm03

Information is obtained from the first 12 hours of admission to your PICU.

Section: Cardiovascular

1.	Temperature (any route)	LOWEST templo	C	HIGHEST temphi	C
2.	Heart rate (do not count during agitation)	LOWEST hrlo	bpm	HIGHEST hrhi	bpm
3.	Systolic blood pressure	LOWEST sbplo	mmHg	HIGHEST sbphi	mmHg

Section: Neurological Status

- Do not assess mental status within 2 hours of sedation, paralysis or anesthesia.
- If there is constant paralysis and/or sedation, use the time period without sedation, paralysis or anesthesia closest to the PICU admission.

4.	Worst pupillary response (Do not assess after iatrogenic dilation)	<input type="radio"/> Both reactive (1) <input type="radio"/> One nonreactive (> 3 mm) (2) prismpup <input type="radio"/> Both nonreactive (> 3 mm) (3)
5.	Worst Glasgow Coma Score (3 elements collected at same time)	Eye opening: prismeye <input type="radio"/> (4) Spontaneous <input type="radio"/> (3) To speech <input type="radio"/> (2) To pain <input type="radio"/> (1) None <input type="radio"/> Not done (0) Best verbal: prismverbal <input type="radio"/> (5) Oriented/smiles, fixes and follows <input type="radio"/> (4) Confused conversation/irritable cries <input type="radio"/> (3) Inappropriate words/cries to pain <input type="radio"/> (2) Incomprehensible sounds/moans to pain <input type="radio"/> (1) None <input type="radio"/> Not done (0) Best motor response: prismmotor <input type="radio"/> (6) Obeys commands, normal spontaneous movement <input type="radio"/> (5) Localizes/withdraws to touch <input type="radio"/> (4) Withdraws to pain <input type="radio"/> (3) Decorticate-abnormal flexion <input type="radio"/> (2) Decerebrate-abnormal extension <input type="radio"/> (1) None <input type="radio"/> Not done (0)

6.	Worst level of consciousness	<input type="radio"/> Normal (1) prismconsc <input type="radio"/> Lethargy: arousable with stimulation to a state capable of communication, associated with an acute process (2) <input type="radio"/> Stupor: arousable with vigorous and repeated stimulation to withdrawal and/or moaning, associated with an acute process (3) <input type="radio"/> Coma: non-purposeful, or no response to vigorous stimulation, associated with an acute process (4) <input type="radio"/> None of the above - chronic altered mental status, no change from the patient's baseline (5)
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Section: Blood Studies

- Use only the first 12 hours of admission to your PICU.
- Chart single draws in Highest column and check the "One Draw Only" box.
- If test not done, check the "Not Done" box.

7.	pH (arterial, venous, capillary)	LOWEST phlo	HIGHEST phhi	<input type="checkbox"/> One Draw Only ph1	<input type="checkbox"/> Not Done phnd		
8.	PCO ₂ (arterial, venous, capillary)	LOWEST pco2lo	mmHg	HIGHEST pco2hi	mmHg	<input type="checkbox"/> One Draw Only pco21	<input type="checkbox"/> Not Done pco2nd
9.	PaO ₂ (arterial only)	LOWEST pao2lo	mmHg	<input type="checkbox"/> Not Done pao2nd			
10.	Potassium	LOWEST klo	mmol/L	HIGHEST khi	mmol/L	<input type="checkbox"/> One Draw Only k1	<input type="checkbox"/> Not Done knd
11.	Total CO ₂ (may use calculated HCO ₃ level if TCO ₂ not measured)	LOWEST co2lo	mmol/L	HIGHEST co2hi	mmol/L	<input type="checkbox"/> One Draw Only co21	<input type="checkbox"/> Not Done co2nd
12.	Glucose	LOWEST gluclo	mg/dL	HIGHEST gluchi	mg/dL	<input type="checkbox"/> One Draw Only gluc1	<input type="checkbox"/> Not Done glucnd
13.	BUN	HIGHEST bunhi	mg/dL	<input type="checkbox"/> Not Done bunnd			
14.	Creatinine	HIGHEST creathi	mg/dL	<input type="checkbox"/> Not Done creatnd			
15.	White Blood Count	LOWEST wbclo	K/ μ L	HIGHEST wbchi	K/ μ L	<input type="checkbox"/> One Draw Only wbc1	<input type="checkbox"/> Not Done wbcnd
16.	Platelet count	LOWEST platelo	K/ μ L	HIGHEST platehi	K/ μ L	<input type="checkbox"/> One Draw Only plate1	<input type="checkbox"/> Not Done platend
17.	Prothrombin Time (PT)	HIGHEST pthi	sec	<input type="checkbox"/> Not Done ptnd			
18.	Partial Thromboplastin Time (PTT)	HIGHEST ptthi		<input type="checkbox"/> Not Done pttnd			

		<input type="text"/> sec
19.	AST (SGOT)	HIGHEST <input type="checkbox"/> Not Done asthi U/L astnd
Section: General Information		
20.	Was the patient admitted to the PICU from an inpatient location (excluding the operating or recovery room)?	<input type="radio"/> Yes(1) <input type="radio"/> No(0) inpatient
21.	Was the patient admitted to the PICU for post-operative care within 24 hours following surgical procedure?	<input type="radio"/> Yes(1) <input type="radio"/> No(0) postop
22.	Did the patient have any previous PICU admissions during this hospitalization?	<input type="radio"/> Yes(1) <input type="radio"/> No(0) prevadm
23.	Was the patient admitted with an acute diagnosis of diabetes (i.e., DKA) as the primary reason for PICU admission?	<input type="radio"/> Yes (1) <input type="radio"/> No (0) diabetes
24.	Was the patient admitted with an acute or chronic diagnosis of oncologic disease (cancer)?	<input type="radio"/> Yes(1) <input type="radio"/> No(0) cancer
25.	Was the patient admitted with an acute diagnosis of non-operative cardiovascular disease?	<input type="radio"/> Yes <input type="radio"/> No nonop
26.	Did the patient have a pre-ICU CPR that required cardiac massage during this hospitalization?	<input type="radio"/> Yes (1) <input type="radio"/> No (0) cpr
27.	Does the patient have a known chromosomal abnormality such as an extra chromosome, a long or short arm deletion, or a long or short arm addition?	<input type="radio"/> Yes(1) <input type="radio"/> No(0) chromabn

Form 4a: PICU_Comfort

Data should reflect 24-hour period (00:00 - 23:59).

1.	Was the patient intubated and mechanically ventilated this study day? If No, skip to "Pain Scores" section.	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	intubcomf
2.	Did the patient receive a neuromuscular blocking agent this study day? If No, skip to "SBS Scores" section.	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	nmb
3.	How often did the patient receive a neuromuscular blocking agent this study day?	<input type="radio"/> Intermittent dose(s) to assure immobility during a procedure - Skip to "SBS Scores" section. (1) <input type="radio"/> PRN dose(s) to facilitate mechanical ventilation - Skip to "SBS Scores" section. (2) <input type="radio"/> For more than an hour to facilitate mechanical ventilation - Continue to "For patients chemically paralyzed" section (3)	nmboften

For patients chemically paralyzed for any part of this study day:

4.	Number of hours assessed for agitation in this study day	0-24 ▾	agithr
5.	Number of hours assumed agitation present (AAP) in this study day	0-24 ▾	aaphr
6.	Number of hours assessed for pain in this study day	0-24 ▾	painhr
7.	Number of hours assumed pain present (APP) in this study day	0-24 ▾	apphr
8.	Did the patient receive a neuromuscular blocking agent this <u>entire</u> study day and therefore had no SBS assessments? If Yes, skip to "Comfort Medications - Narcotics" section.	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	nmbentire

Section: SBS Scores

9.	SBS score closest to <u>08:00</u>	▾ -3, -2, -1, 0, 1, 2	sbs8
10.	<u>Lowest</u> SBS score in study day	▾ -3, -2, -1, 0, 1, 2	sbslo
11.	<u>Highest</u> SBS score in study day	▾ -3, -2, -1, 0, 1, 2	sbshi
12.	Was a neuromuscular blocking agent used to manage agitation?	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	nmbagit
13.	SBS score occurring <u>most</u> often in study day (modal)	▾ -3, -2, -1, 0, 1, 2	sbsmod

14.	Were SBS scores documented per <i>RESTORE</i> this study day?	<input type="radio"/> Yes (SBS Q4H when patient not chemically paralyzed, AAP Q2H when patient chemically paralyzed, no SBS scores when patient is extubated) (1) sbsdoc <input type="radio"/> No (0)
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Section: Pain Scores

15.	Pain assessment tool used closest to <u>08:00</u>	<input type="radio"/> FLACC (1) <input type="radio"/> FACES (2) paintool <input type="radio"/> NRS/VAS (3) <input type="radio"/> Individualized NRS (4) <input type="radio"/> Other, (99) paintooloth specify:
16.	Pain score closest to <u>08:00</u>	0-10 <input type="text"/> pain8
17.	<u>Lowest</u> pain score in study day	0-10 <input type="text"/> painlo
18.	<u>Highest</u> pain score in study day	0-10 <input type="text"/> painhi
19.	Pain score occurring <u>most often</u> in study day (modal)	0-10 <input type="text"/> painmod
20.	Were pain scores documented per <i>RESTORE</i> this study day?	<input type="radio"/> Yes (pain scores using specified pain tool Q4H when patient not chemically paralyzed, APP Q2H when patient chemically paralyzed) (1) paindoc <input type="radio"/> No (0)

Section: Comfort Medications - Narcotics

21.	Did the patient receive narcotics on this study day? If No, skip to "Comfort Medications - Benzodiazepines" section.	<input type="radio"/> Yes (1) <input type="radio"/> No (0) narc
22.	Were continuous infusions of narcotics administered?	<input type="radio"/> Yes (1) narccont If Yes, were continuous infusions of narcotics temporarily discontinued at any time on this study day? <input type="radio"/> Yes (1) narcdiscon If Yes, how long were the narcotics temporarily discontinued on this study day (in minutes): narcdisdur <input type="radio"/> No (0) <input type="radio"/> No (0)
23.	Were scheduled intermittent doses of narcotics administered?	<input type="radio"/> Yes (1) narcint If Yes, how administered? narcintroute <input type="radio"/> IV (1) <input type="radio"/> Enteral (2) <input type="radio"/> IV and Enteral (3)

		<input type="radio"/> No (0)
24.	<p>Were PRN bolus or one time doses of narcotics administered?</p>	<input type="radio"/> Yes (1) narcbol <p>If Yes, specify the combined total of the number of PRN and one time narcotic doses this study day (1-99): narcbolno</p> <p>How administered? narcbolroute</p> <input type="radio"/> IV (1) <input type="radio"/> Enteral (2) <input type="radio"/> IV and Enteral (3) <input type="radio"/> No (0)
25.	<p>Total combined morphine this study day</p> <p>Note: 24-hour dose calculation tool on <i>RESTORE</i> study website.</p>	morphtot mg/24 hours
26.	<p>Total combined fentanyl this study day</p>	fenttot mcg/24 hours
27.	<p>Total combined methadone this study day</p>	methtot mg/24 hours
28.	<p>Is the patient weaning from \geq 5 days of continuous, intermittent, or prn narcotics?</p>	<input type="radio"/> Yes (1) narcwean5 <input type="radio"/> No (0)
Section: Comfort Medications - Benzodiazepines		
29.	<p>Did the patient receive benzodiazepines on this study day?</p> <p>If No, skip to "Other Comfort Medications" section.</p>	<input type="radio"/> Yes (1) <input type="radio"/> No (0) benz
30.	<p>Were continuous infusions of benzodiazepines administered?</p>	<input type="radio"/> Yes (1) benzcont <p>If Yes, were continuous infusions of benzodiazepines temporarily discontinued at any time on this study day?</p> <input type="radio"/> Yes (1) benzdiscon <p>If Yes, how long were the benzodiazepines temporarily discontinued on this day (in minutes):</p> benzdisdur <input type="radio"/> No(0) <input type="radio"/> No (0)
31.	<p>Were scheduled intermittent doses of benzodiazepines administered?</p>	<input type="radio"/> Yes (1) benzint <p>If Yes, how administered?</p>

		<input type="radio"/> IV (1) <input type="radio"/> Enteral (2) benzinroute <input type="radio"/> IV and Enteral (3) <input type="radio"/> No (0)
32.	Were PRN bolus or one time doses of benzodiazepines administered?	<input type="radio"/> Yes (1) benzbol <p>If Yes, specify the combined total of the number of PRN and one time benzodiazepine doses this study day (1-99):</p> <p>benzbolno</p> <p>How administered?</p> <input type="radio"/> IV (1) <input type="radio"/> Enteral (2) benzbolroute <input type="radio"/> IV and Enteral (3) <input type="radio"/> No (0)
33.	Total combined midazolam this study day	midaztot mg/24 hours
34.	Total combined lorazepam this study day	loraztot mg/24 hours
Section: Other Comfort Medications		
35.	Did the patient receive other comfort medications on this study day? If Yes, "Add entry" for each other comfort medication.	<input type="radio"/> Yes(1) <input type="radio"/> No (0) comfmed
Other Comfort Medications Entry		
36.1	Select the other comfort medication	<input type="button" value="v"/> Pulldown list 3 comfmedcode1, ..., comfmedcode7
36.2	If Other, specify	comfmedoth1, ..., comfmedoth7
36.3	Total 24-hour dose of this other comfort medication	<input type="radio"/> mg/24 hours ⁽¹⁾ <input type="radio"/> mcg/24 hours (2) comfmedtot_unit1, ..., comfmedtot_unit7 comfmedtot1, ..., comfmedtot7
Section: Medications for Other Reasons		
37.	Did the patient receive any medications to facilitate sleep on this study day?	<input type="radio"/> Yes, select the medication: <input type="button" value="v"/> Pulldown list 3 sleepmedcode sleepmed <input type="radio"/> If Other, specify: sleepmedoth

		<p>Total 24-hour dose of this sleep agents <input type="radio"/> mg/24 hours ⁽¹⁾ <input type="radio"/> mcg/24 hours (2) <input type="radio"/> No (0) sleepmedtot sleepmedtot_unit</p>
38.	<p>Did patient receive any medications to manage delirium on this study day?</p>	<p><input type="radio"/> Yes, select the medication: <input type="button" value="v"/> Pulldown list 3 delmedcode delmed (1) If delmedoth Other, specify: Total 24-hour dose of this delirium agent: delmedtot <input type="radio"/> mg/24 hours ⁽¹⁾ <input type="radio"/> mcg/24 hours (2) <input type="radio"/> No (0) delmedtot_unit</p>
39.	<p>Did the patient receive any of these medications for any other reason on this study day?</p>	<p><input type="radio"/> Yes(1) medother Select the medication(s): <input type="checkbox"/> Acetaminophen (Tylenol) mg medother_acetam <input type="checkbox"/> Tylenol with codeine mg medother_tylcod <input type="checkbox"/> Chloral Hydrate (Aquachloral) mg medother_ch <input type="checkbox"/> Clonazepam (Klonopin) mg medother_clonaz <input type="checkbox"/> Clonidine (Catapres) mcg medother_clon <input type="checkbox"/> Codeine mg medother_cod <input type="checkbox"/> Dexmedetomidine (Precedex) mcg medother_dex <input type="checkbox"/> Diazepam (Valium) mg medother_diaz <input type="checkbox"/> Diphenhydramine (Benadryl) mg medother_diphen <input type="checkbox"/> Droperidol (Inapsine) mg medother_drop <input type="checkbox"/> Etomidate (Amidate) mg medother_etom <input type="checkbox"/> Flumazenil (Romazicon) mg medother_flum <input type="checkbox"/> Haloperidol (Haldol) mg medother_halo <input type="checkbox"/> Hydromorphone (Dilaudid) mg medother_hydromor <input type="checkbox"/> Hydroxyzine (Atarx, Vistaril) mg medother_hydroxyz <input type="checkbox"/> Ibuprofen (Advil, Motrin) mg medother_ibu <input type="checkbox"/> Ketamine (Ketalar) mg medother_ket <input type="checkbox"/> Ketorolac (Toradol) mg medother_ketoro <input type="checkbox"/> Melatonin mg medother_mel <input type="checkbox"/> Meperidine (Demerol) mg medother_mep <input type="checkbox"/> Nalbuphine Hydrochloride (Nubain) mg medother_nalbu <input type="checkbox"/> Naloxone Hydrochloride (Narcan) mg medother_nalox <input type="checkbox"/> Olanzapine (Zyprexa) mg medother_olanz <input type="checkbox"/> Oxycodone immediate release (Oxycontin) mg medother_oxycodir <input type="checkbox"/> Oxycodone sustained release (Oxycontin) mg medother_oxycodsr <input type="checkbox"/> Pentobarbital (Nembutal) mg medother_pento</p>

- Pentothal sodium (Thiopental) mg **medother_pentothal**
- Phenobarbital (Luminal) mg **medother_pheno**
- Propofol (Diprivan) mcg **medother_prop**
- Risperidone (Risperdal) mg **medother_risp**
- Sufentanil (Sufenta) mcg **medother_suf**
- Sweet-Ease (oral sucrose) *(dose not required) **medother_sweetease**
- Zolpidem (Ambien) mg **medother_zol**
- Any inhalation anesthetic *(dose not required) **medother_inhalan**
- Other **medother_other**

If
Other,
specify:

~~medotheroth~~

Note: Removed (not applicable)

No (0)

RESTORE: Form 4a: PICU_Neuro

Form 4a: PICU_Neuro

1. Pupillary response (closest to 08:00)	<input type="radio"/> Both reactive (1) pup <input type="radio"/> One nonreactive (> 3 mm) (2) <input type="radio"/> Both nonreactive (> 3 mm) (3)
2. Glasgow Coma Score (closest to 08:00)	Eye opening: gcseye <input type="radio"/> (4) Spontaneous <input type="radio"/> (3) To speech <input type="radio"/> (2) To pain <input type="radio"/> (1) None <input type="radio"/> Not done (0) Best verbal (if patient intubated, give best estimate): gcsverbal <input type="radio"/> (5) Oriented/smiles, fixes and follows <input type="radio"/> (4) Confused conversation/irritable cries <input type="radio"/> (3) Inappropriate words/cries to pain <input type="radio"/> (2) Incomprehensible sounds/moans to pain <input type="radio"/> (1) None <input type="radio"/> Not done (0) Best motor response: gcsmotor <input type="radio"/> (6) Obeys commands, normal spontaneous movement <input type="radio"/> (5) Localizes/withdraws to touch <input type="radio"/> (4) Withdraws to pain <input type="radio"/> (3) Decorticate-abnormal flexion <input type="radio"/> (2) Decerebrate-abnormal extension <input type="radio"/> (1) None <input type="radio"/> Not done (0)
3. Worst level of consciousness (closest to 08:00)	<input type="radio"/> Normal (1) consc <input type="radio"/> Lethargy: Arousable with stimulation to a state capable of communication, associated with an acute process (2) <input type="radio"/> Stupor: Arousable with vigorous and repeated stimulation to withdraw and/or moaning, associated with an acute process (3) <input type="radio"/> Coma: Nonpurposeful, or no response to vigorous stimulation, associated with an acute process (4) <input type="radio"/> Not assessed (5) <input type="radio"/> None of the above - chronic altered mental status, no change from the patient's baseline (6)
4. Were any of the following neurological tests performed <u>on this study day</u> ?	Brain CT: brainct <input type="radio"/> Yes(1) <input type="radio"/> No (0)

Brain MRI: **brainmri**

Yes (1)

No(0)

Lumbar puncture: **lumbar**

Yes (1)

No(0)

RESTORE: Form 4a: PICU_Resp_Labs

Section: Respiratory Support

1.	Was there assisted breathing on this study day? If No, skip to "Respiratory Assessments" section. For questions 2 through 6, number of hours/day should add up to number of hours on DOV tab.	<input type="radio"/> Yes (1) astbr <input type="radio"/> No (0)	
Note: A value of Yes and 0 indicates 29 minutes or less			
2.	None	<input type="radio"/> Yes, # hours/day: 0-24 <input type="text" value=""/> (1) nonehr <input type="radio"/> No (0)	none
3.	CPAP \geq 5 cm H ₂ O	<input type="radio"/> Yes, # hours/day: 0-24 <input type="text" value=""/> (1) cpaphr <input type="radio"/> No (0)	cpap
4.	Humidified High Flow Nasal Cannula (HHFNC \geq 5 L/min of Oxygen flow)	<input type="radio"/> Yes, # hours/day: 0-24 <input type="text" value=""/> (1) hhfnchr <input type="radio"/> No (0)	hhfnc
5.	BiPAP	<input type="radio"/> Yes, # hours/day: 0-24 <input type="text" value=""/> (1) bipaphr <input type="radio"/> No (0)	bipap
6.	Ventilator If No, skip to "Respiratory Assessments" section. For questions 8 through 11, number of hours/day should add up to # hours/day recorded in question 6.	<input type="radio"/> Yes, # hours/day: 0-24 <input type="text" value=""/> (1) venthr <input type="radio"/> No (0)	vent
7.	If on ventilator, was the patient spontaneously breathing at 08:00?	<input type="radio"/> Yes (1) spontbr08 <input type="radio"/> No (0)	
8.	Ventilator mode: Spontaneous without a set back up rate	<input type="radio"/> Yes, # hours/day: 0-24 <input type="text" value=""/> (1) sponworatehr <input type="radio"/> No (0)	sponworate
9.	Ventilator mode: Spontaneous with a set back up rate	<input type="radio"/> Yes, # hours/day: 0-24 <input type="text" value=""/> (1) sponwratehr <input type="radio"/> No (0)	sponwrate
10.	Ventilator mode: Controlled only (no spontaneous breathing)	<input type="radio"/> Yes, # hours/day: 0-24 <input type="text" value=""/> (1) controlmodehr <input type="radio"/> No (0)	controlmode
11.	Ventilator mode: HFOV	<input type="radio"/> Yes, # hours/day: 0-24 <input type="text" value=""/> (1) hfovhr <input type="radio"/> No (0)	hfov

Section: Respiratory Assessments

For questions 12 through 15, record values that were measured simultaneously closest to 08:00.

12.	PaO ₂	<input type="text" value="pao2"/> mmHg <input type="checkbox"/> No arterial specimen <input type="checkbox"/> On ECMO pao2ecmo pao2nospec
13.	Mean airway pressure	<input type="text" value="map"/> cm H ₂ O <input type="checkbox"/> No airway pressure <input type="checkbox"/> On ECMO mapecmo mapnopres
14.	FiO ₂	<input type="text" value="fio2"/> <input type="checkbox"/> Not on assisted breathing fio2notab
15.	SpO ₂ (pulse oximetry)	<input type="text" value="spo2"/> %
16.	Was a chest x-ray obtained on this study day?	<input type="radio"/> Yes (1) respixray If Yes, is this the first study day that <u>new</u> bilateral infiltrates/opacities were identified? <input type="radio"/> Yes (1) respbilat <input type="radio"/> No (0) <input type="radio"/> No (0)
17.	Is this patient showing evidence of left atrial (LA) hypertension (e.g., ECHO+) on this study day?	<input type="radio"/> Yes (1) resplaht <input type="radio"/> No (0)

Section: Extubation

18.	Was this patient intubated or did this patient remain intubated this study day? If No, skip to "Labs" section.	<input type="radio"/> Yes (1) intub If Yes, does patient have ETT air leak on this study day? airleak <input type="radio"/> Yes (1) <input type="radio"/> No (0) <input type="radio"/> Not measured (2) <input type="radio"/> No (0)
19.	Was this patient extubated on this study day? If Yes, "Add entry" for each extubation this study day. If No, skip to "Labs" section.	<input type="radio"/> Yes (1) extub <input type="radio"/> No (0)

Extubation Entry

20.1	Extubation time	<input type="text" value=""/> : <input type="text" value=""/> <i>24-hour clock</i> Note: Changed to hours since intubation extub_hrssinceintub1, ..., extub_hrssinceintub3
20.2	Extubation type If unplanned extubation, complete a Form 9: Adverse Events.	<input type="radio"/> Planned (passed ERT) (1) <input type="radio"/> Planned (no ERT or failed ERT) (2) extubtype1, ..., extubtype3 <input type="radio"/> Unplanned extubation without soft restraints (3) <input type="radio"/> Unplanned extubation with soft restraints (4)

20.3 Reintubated within 24 hours?

If reintubated, complete a Form 9: Adverse Events.

Yes (1) **reintub1, ..., reintub3**

If Yes, reintubation date and time:

| / | / |

| : | 24-hour clock

Note: Changed to hours since extubation
reintub_hrssinceextub1, ..., reintub_hrssinceextub3

Reason patient was reintubated: **reintubcode1, ..., reintubcode3**

- Upper airway - stridor, hypoxia/hypercarbia (1)
- Lower respiratory - hypoxia/hypercarbia (2)
- Insufficient respiratory effort due to over sedation (3)
- Insufficient respiratory effort due to neuromuscular fatigue (4)
- Insufficient respiratory effort due to neurologic status (5)
- Planned surgery or other procedure requiring deep sedation (6)
- Excessive secretions that could not be adequately cleared (7)
- ETT size/ETT location change (8)
- Other, (99) **reintubcodeoth1, ..., reintubcodeoth3**
specify:

No (0)

Section: Labs

If obtained more than once, record results closest to 08:00. If test not done, check the "Not Done" box.

21.	BUN	bun	mg/dL	<input type="checkbox"/> Not Done	bunndlabs
22.	Creatinine	creat	mg/dL	<input type="checkbox"/> Not Done	creatndlabs
23.	ALT	alt	U/L	<input type="checkbox"/> Not Done	altndlabs
24.	Total Bilirubin	bilitot	mg/dL	<input type="checkbox"/> Not Done	bilitotndlabs
25.	Direct Bilirubin	bilidirect	mg/dL	<input type="checkbox"/> Not Done	bilidirndlabs
26.	Prothrombin Time (PT)	pt	sec	<input type="checkbox"/> Not Done	ptndlabs
27.	Albumin	alb	g/dL	<input type="checkbox"/> Not Done	albndlabs
28.	Total Protein	totprot	g/dL	<input type="checkbox"/> Not Done	totprotndlabs
29.	White Blood Count	wbc	K/ μ L	<input type="checkbox"/> Not Done	wbcndlabs
30.	Platelet count	plate	K/ μ L	<input type="checkbox"/> Not Done	platendlabs

RESTORE: Form 4a: PICU_Misc

Section: Miscellaneous

1. Any vasoactive medications	<input type="radio"/> None (1) <input type="radio"/> Single (2) vasoactive <input type="radio"/> Multiple (3)
2. Any dialysis technique	<input type="radio"/> Yes (1) <input type="radio"/> No (0) dialysis
3. Any supplemental oxygen (any delivery device)	<input type="radio"/> Yes (1) <input type="radio"/> No (0) supplo2
4. ICU-only interventions (e.g., ECMO cannulation, pacemaker, cardioversion, endoscopy, emergency operation, gastric lavage) Note: Routine interventions such as x-rays, echocardiography, electrocardiography, dressings, and venous or arterial line are not included.	<input type="radio"/> Yes (1) <input type="radio"/> No (0) icuint
5. Patient escorted outside the ICU for any intervention (e.g., surgery, diagnostic procedure)	<input type="radio"/> Yes (1) <input type="radio"/> No (0) outicuint
6. Devices <u>this study day</u>	Arterial line: art <input type="radio"/> Existing(1) <input type="radio"/> New(2) <input type="radio"/> None (0) Central venous line: cvl <input type="radio"/> Existing(1) <input type="radio"/> New(2) <input type="radio"/> None (0) Peripheral IV: pvl <input type="radio"/> Existing(1) <input type="radio"/> New(2) <input type="radio"/> None (0) Nasogastric tube: ngtube <input type="radio"/> Existing(1) <input type="radio"/> New(2) <input type="radio"/> None (0) Bladder catheter: bladcath <input type="radio"/> Existing(1) <input type="radio"/> New(2) <input type="radio"/> None (0) Chest tube: chesttube <input type="radio"/> Existing(1) <input type="radio"/> New(2) <input type="radio"/> None (0) Surgical wound drain: wounddrain <input type="radio"/> Existing(1) <input type="radio"/> New(2) <input type="radio"/> None (0)

Section: Event Log

7. Identify all events that occurred <u>this study day</u> (check all that apply):	<input type="checkbox"/> Inadequate pain management eventlog_ipm <input type="checkbox"/> Inadequate sedation management eventlog_ism
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If any event, complete a Form 9: Adverse Events form.

- Clinically significant iatrogenic withdrawal [eventlog_csiw](#)
- Unplanned ETT extubation [eventlog_selfextub](#)
- Post extubation stridor with chest-wall retractions at rest [eventlog_stridor](#)
- Extubation failure - reintubation within 24 hours [eventlog_extubfail](#)
- Unplanned removal of arterial access [eventlog_art](#)
- Unplanned removal of central venous access [eventlog_cvl](#)
- Unplanned removal of peripheral venous access [eventlog_pvl](#)
- Unplanned removal of nasogastric drainage tube [eventlog_ngtube](#)
- Unplanned removal of bladder catheter Note: Responses of unplanned removal of bladder catheter, chest tube, and other tube were collapsed to other tube
- Unplanned removal of chest tube Note: Removed for duplicity (see Form 9)
- Unplanned removal of "other" tube, specify: ~~[eventothtube](#)~~ [eventlog_othtube](#)
- Ventilator-associated pneumonia (new this study day) [eventlog_vap](#)
- Catheter-associated bloodstream infection (new this study day) [eventlog_cabsi](#)
- Stage 2+ pressure ulcers (new this study day) [eventlog_ulcer](#)
- Tracheostomy (new this study day) [eventlog_trach](#)
- Other, specify: ~~[eventoth](#)~~ [eventlog_othevent](#) Note: Removed for duplicity (see Form 9)
- None [eventlog_noevent](#)

Section: Patient Status

8. Was a WAT-1 performed on this study day?

- Yes - **Complete Form 7.** (1) [wat](#)
- No (0)

9. Has the patient been discharged from the *RESTORE* study on this study day?

- Yes - **No further daily forms are needed. Proceed to Form 8.** (1) [studydis](#)
- If Yes, specify reason for study discharge:
- Pulldown list 4 [studydisreas](#)
- No (0)

Section: Patient Trajectory

1. Was the trajectory of illness identified on this study day?

If acute, titration, or weaning phase, skip to appropriate section.**If short-term, No, or Not yet enrolled in study, skip to "Form 4b: Comfort" tab.** Not yet enrolled in study - study day prior to consent (2) **trajectiden** Yes (1)Identified trajectory of illness: **trajectill** Short-term (anticipated) length of intubation < 48 hours (1) Acute Phase (2) Titration Phase (3) Weaning Phase (4) No (0)**Section: Acute Phase**2. Were drips increased for ≥ 3 non-procedural boluses Q8H? Yes (1) **acdripinc** No (0)If No, were drips not increased for ≥ 3 non-procedural boluses Q8H because hypotension was present? **acdripinchypo** Yes (1) No (0) N/A (< 3 non-procedural boluses given in any 8 hour period) (2)**Section: Titration Phase**

3. If morning SBS is -3, was an arousal assessment performed?

 Yes (1) **tiaa**If Yes, did the patient achieve an awake state (SBS -1 or 0)? **tiaaawake** Yes (1) No (0)

Indicate the total time the sedatives were turned off (in minutes):

tiaaminAt the end of the arousal assessment: **tiaaendpt** Sedation infusion restarted at 50% (1) Arousal assessment aborted because SBS > 0 (2) Sedation infusion discontinued because the patient did not arouse (3) No (0) N/A (SBS not -3) (2)

4. If morning SBS is -2, was a modified arousal assessment performed?

 Yes (1) **timodaa**If Yes, did the patient achieve an awake state (SBS -1 or 0)? **timodaaawake**

	<input type="radio"/> Yes (1) <input type="radio"/> No (0) Indicate the total time the sedative infusions were reduced by 50% (in minutes): timodaamin At the end of the modified arousal assessment: timodaaendpt <input type="radio"/> Patient required 1-2 rescue sedation bolus dosages but sedation infusion was maintained at 50% (1) <input type="radio"/> Patient required 3 rescue sedation bolus dosages and the sedation infusion(s) increased (4) <input type="radio"/> Modified arousal assessment aborted because SBS > 0(2) <input type="radio"/> Sedation infusion discontinued because the patient did not arouse(3) <input type="radio"/> No(0) <input type="radio"/> N/A (SBS not -2) (2)
5. Were drips increased for ≥ 3 non-procedural boluses Q8H?	<input type="radio"/> Yes (1) tidripinc <input type="radio"/> No(0) <input type="radio"/> N/A (< 3 non-procedural boluses given in any 8 hour period) (2)
6. Were drips decreased for ≤ 2 non-procedural boluses Q8H?	<input type="radio"/> Yes (1) tidripdec <input type="radio"/> No (0) <input type="radio"/> N/A (> 2 non-procedural boluses given in any 8 hour period) (2)
Section: Weaning Phase	
7. If morning SBS is -3, was an arousal assessment performed?	<input type="radio"/> Yes (1) weanaa If Yes, did the patient achieve an awake state (SBS -1 or 0)? weanaaawake <input type="radio"/> Yes (1) <input type="radio"/> No (0) Indicate the total time the sedatives were turned off (in minutes): weanaamin At the end of the arousal assessment: weanaaendpt <input type="radio"/> Sedation infusion restarted at 50%(1) <input type="radio"/> Arousal assessment aborted because SBS > 0(2) <input type="radio"/> Sedation infusion discontinued because the patient did not arouse (3) <input type="radio"/> No(0) <input type="radio"/> N/A (SBS not -3)(2)
8. If morning SBS is -2, was a modified arousal assessment performed?	<input type="radio"/> Yes (1) weanmodaa

	<p>If Yes, did the patient achieve an awake state (SBS -1 or 0)?</p> <p><input type="radio"/> Yes (1) weanmodaaawake</p> <p><input type="radio"/> No (0)</p> <p>Indicate the total time the sedative infusions were reduced by 50% (in minutes):</p> <p>weanmodaamin</p> <p>At the end of the modified arousal assessment: weanmodaaendpt</p> <p><input type="radio"/> Patient required 1-2 rescue sedation bolus dosages but sedation infusion was maintained at 50% (1)</p> <p><input type="radio"/> Patient required 3 rescue sedation bolus dosages and the sedation infusion(s) increased (4)</p> <p><input type="radio"/> Modified arousal assessment aborted because SBS > 0 (2)</p> <p><input type="radio"/> Sedation infusion discontinued because the patient did not arouse (3)</p> <p><input type="radio"/> No(0)</p> <p><input type="radio"/> N/A (SBS not -2) (2)</p>
<p>9. Did the patient receive \geq 5 days of comfort medications?</p>	<p><input type="radio"/> Yes (1) wean5days</p> <p><input type="radio"/> No(0)</p> <p>If No, were narcotics and benzodiazepines infusions discontinued per protocol on this study day? weandripdiscon</p> <p><input type="radio"/> Yes (1)</p> <p><input type="radio"/> No(0)</p> <p><input type="radio"/> N/A (infusions previously discontinued)(2)</p> <p style="text-align: center;">Skip to "Form 4b: Comfort" tab.</p>
<p>10. Were narcotics weaned per protocol on this study day?</p>	<p><input type="radio"/> Yes (1)</p> <p><input type="radio"/> No(0)</p> <p><input type="radio"/> N/A (narcotic wean complete) (2)</p> <p style="text-align: right;">weannarc</p>
<p>11. Were benzodiazepines weaned per protocol on this study day?</p>	<p><input type="radio"/> Yes (1)</p> <p><input type="radio"/> No (0)</p> <p><input type="radio"/> N/A (Bz wean complete)(2)</p> <p style="text-align: right;">weanbenz</p>
<p>12. Were narcotics and benzodiazepines weaned at the same time during this study day?</p>	<p><input type="radio"/> Yes (1)</p> <p><input type="radio"/> No (0)</p> <p><input type="radio"/> N/A (narcotic or Bz wean complete) (2)</p> <p style="text-align: right;">weansame</p>
<p>13. Was a maximum WAT-1 score identified on this study day?</p> <p>If No, skip over next question.</p>	<p><input type="radio"/> Yes (1) weanmaxwat1</p> <p>If Yes, what was the maximum WAT-1 score? maxwat1</p> <p>0-12 <input type="text" value="0-12"/></p>

		<input type="radio"/> No(0)	
14.	Did the patient score higher than the maximum WAT-1 score on this study day?	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	weanhighwat
15.	Was clonidine administered this study day?	<input type="radio"/> Yes (1) <input type="radio"/> No(0)	weanclonidine
16.	Was methadone administered this study day?	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	weanmethadone
17.	Was the WAT-1 documented every 12 hours on this study day?	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	weanwatdoc12

RESTORE: Form 4b: PICU_Comfort

Form 4b: PICU_Comfort

1.	Was the patient intubated and mechanically ventilated this study day? If No, skip to "Pain Scores" section.	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	intubcomf
2.	Did the patient receive a neuromuscular blocking agent this study day? If No, skip to "SBS Scores" section.	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	nmb
3.	How often did the patient receive a neuromuscular blocking agent this study day?	<input type="radio"/> Intermittent dose(s) to assure immobility during a procedure - Skip to "SBS Scores" section. (1) <input type="radio"/> PRN dose(s) to facilitate mechanical ventilation - Skip to "SBS Scores" section. (2) <input type="radio"/> For more than an hour to facilitate mechanical ventilation - Continue to "For patients chemically paralyzed" section (3)	nmboften

For patients chemically paralyzed for any part of this study day:

4.	Number of hours assessed for agitation in this study day	0-24 <input type="text"/>	agithr
5.	Number of hours assumed agitation present (AAP) in this study day	0-24 <input type="text"/>	aaphr
6.	Number of hours assessed for pain in this study day	0-24 <input type="text"/>	painhr
7.	Number of hours assumed pain present (APP) in this study day	0-24 <input type="text"/>	apphr
8.	Did the patient receive a neuromuscular blocking agent this <u>entire</u> study day and therefore had no SBS assessments? If Yes, skip to "Comfort Medications - Narcotics" section.	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	nmbentire

Section: SBS Scores

9.	First prescribed target SBS score this study day	<input type="text"/> -3, -2, -1, 0, 1, 2, (88) Not prescribed	sbsta
10.	Number of hours in this study day that patient remained within first prescribed SBS score	0-24 <input type="text"/> (25) N/A	sbstadur
11.	Second prescribed target SBS score this study day	<input type="text"/> -3, -2, -1, 0, 1, 2, (77) Only one SBS prescribed on this day, (88) No SBS prescribed on this day	sbsta2
12.	Number of hours in this study day that patient remained within second prescribed SBS Score	0-24 <input type="text"/> (25) N/A	sbsta2dur

13.	SBS score closest to <u>08:00</u>	<input type="text" value="-3, -2, -1, 0, 1, 2"/>	sbs8
14.	<u>Lowest</u> SBS score in study day	<input type="text" value="-3, -2, -1, 0, 1, 2"/>	sbslo
15.	<u>Highest</u> SBS score in study day	<input type="text" value="-3, -2, -1, 0, 1, 2"/>	sbshi
16.	Was a neuromuscular blocking agent used to manage agitation?	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	nmbagit
17.	SBS score occurring <u>most</u> often in study day (modal)	<input type="text" value="-3, -2, -1, 0, 1, 2"/>	sbsmod
18.	Were SBS scores documented per <i>RESTORE</i> this study day?	<input type="radio"/> Yes (SBS Q4H when patient not chemically paralyzed, AAP Q2H when patient chemically paralyzed, no SBS scores when patient is extubated) (1) <input type="radio"/> No (0)	sbsdoc

Section: Pain Scores

19.	Pain assessment tool used closest to <u>08:00</u>	<input type="radio"/> FLACC(1) <input type="radio"/> FACES (2) <input type="radio"/> NRS/VAS (3) <input type="radio"/> Individualized NRS (4) <input type="radio"/> Other, (99) paintooloth specify:	paintool
20.	Pain score closest to <u>08:00</u>	0-10 <input type="text"/>	pain8
21.	<u>Lowest</u> pain score in study day	0-10 <input type="text"/>	painlo
22.	<u>Highest</u> pain score in study day	0-10 <input type="text"/>	painhi
23.	Pain score occurring <u>most often</u> in study day (modal)	0-10 <input type="text"/>	painmod
24.	Were pain scores documented per <i>RESTORE</i> this study day?	<input type="radio"/> Yes (pain scores using specified pain tool Q4H when patient not chemically paralyzed, APP Q2H when patient chemically paralyzed) (1) <input type="radio"/> No (0)	paindoc

Section: Comfort Medications - Narcotics

25.	Did the patient receive narcotics on this study day? If No, skip to "Comfort Medications - Benzodiazepines" section.	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	narc
26.	Were continuous infusions of narcotics administered?	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	narccont
27.	Were scheduled intermittent doses of narcotics administered?	<input type="radio"/> Yes (1)	narcint

		<p>If Yes, how administered? narcintroute</p> <p><input type="radio"/> IV (1)</p> <p><input type="radio"/> Enteral(2)</p> <p><input type="radio"/> IV and Enteral (3)</p> <p><input type="radio"/> No(0)</p>
28.	Were PRN bolus or one time doses of narcotics administered?	<p><input type="radio"/> Yes (1) narcbol</p> <p>If Yes, specify the combined total of the number of PRN and one time narcotic doses this study day (1-99): narcbolno</p> <p>How administered? narcbolroute</p> <p><input type="radio"/> IV (1)</p> <p><input type="radio"/> Enteral(2)</p> <p><input type="radio"/> IV and Enteral (3)</p> <p><input type="radio"/> No (0)</p>
29.	Total combined morphine this study day Note: 24-hour dose calculation tool on <i>RESTORE</i> study website.	morphtot mg/24 hours
30.	Total combined fentanyl this study day	fenttot mcg/24 hours
31.	Total combined methadone this study day	methtot mg/24 hours
32.	Is the patient weaning from \geq 5 days of continuous, intermittent, or prn narcotics?	<p><input type="radio"/> Yes (1) narcwean5</p> <p><input type="radio"/> No (0)</p>
Section: Comfort Medications - Benzodiazepines		
33.	Did the patient receive benzodiazepines on this study day? If No, skip to "Other Comfort Medications" section.	<p><input type="radio"/> Yes (1)</p> <p><input type="radio"/> No (0) benz</p>
34.	Were continuous infusions of benzodiazepines administered?	<p><input type="radio"/> Yes (1)</p> <p><input type="radio"/> No (0) benzcont</p>
35.	Were scheduled intermittent doses of benzodiazepines administered?	<p><input type="radio"/> Yes (1) benzint</p> <p>If Yes, how administered? benzintroute</p> <p><input type="radio"/> IV (1)</p> <p><input type="radio"/> Enteral(2)</p> <p><input type="radio"/> IV and Enteral (3)</p>

		<input type="radio"/> No (0)
36.	Were PRN bolus or one time doses of benzodiazepines administered?	<input type="radio"/> Yes (1) benzbol If Yes, specify the combined total of the number of PRN and one time benzodiazepine doses this study day (1-99): benzbolno How administered? benzbolroute <input type="radio"/> IV (1) <input type="radio"/> Enteral (2) <input type="radio"/> IV and Enteral (3) <input type="radio"/> No (0)
37.	Total combined midazolam this study day	midaztot mg/24 hours
38.	Total combined lorazepam this study day	loraztot mg/24 hours

Section: Other Comfort Medications

39.	Did the patient receive other comfort medications on this study day? If Yes, "Add entry" for each other comfort medication.	<input type="radio"/> Yes (1) <input type="radio"/> No (0) comfmed
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Other Comfort Medications Entry

40.1	Select the other comfort medication	<input type="button" value="v"/> Pulldown list 3 comfmedcode1, ..., comfmedcode7
40.2	If Other, specify	comfmedoth1, ..., comfmedoth7
40.3	Total 24-hour dose of this other comfort medication	<input type="radio"/> mg/24 hours ⁽¹⁾ <input type="radio"/> mcg/24 hours ⁽²⁾ comfmedtot_unit1, ..., comfmedtot_unit7 comfmedtot1, ..., comfmedtot7

Section: Medications for Other Reasons

41.	Did the patient receive any medications to facilitate sleep on this study day?	<input type="radio"/> Yes, select the medication: <input type="button" value="v"/> Pulldown list 3 sleepmedcode (1) sleepmed If Other, sleepmedoth specify: Total 24-hour dose of this sleep agent: sleepmedtot ⁽¹⁾ <input type="radio"/> mg/24 hours <input type="radio"/> mcg/24 hours ⁽²⁾ sleepmedtot_unit <input type="radio"/> No (0)
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42.	Did patient receive any medications to manage delirium on this study day?	<input type="radio"/> Yes, select the medication: <input type="button" value="v"/> Pulldown list 3 delmedcode (1) delmed If delmedoth Other, specify: Total 24-hour dose of this delirium agent: delmedtot <input type="radio"/> mg/24 hours <input type="radio"/> mcg/24 hours (2) (1) delmedtot_unit <input type="radio"/> No (0)
43.	Did the patient receive any of these medications for any other reason on this study day?	<input type="radio"/> Yes (1) medother Select the medication(s): <input type="checkbox"/> Acetaminophen (Tylenol) mg medother_acetam <input type="checkbox"/> Tylenol with codeine mg medother_tylcod <input type="checkbox"/> Chloral Hydrate (Aquachloral) mg medother_ch <input type="checkbox"/> Clonazepam (Klonopin) mg medother_clonaz <input type="checkbox"/> Clonidine (Catapres) mcg medother_clon <input type="checkbox"/> Codeine mg medother_cod <input type="checkbox"/> Dexmedetomidine (Precedex) mcg medother_dex <input type="checkbox"/> Diazepam (Valium) mg medother_diaz <input type="checkbox"/> Diphenhydramine (Benadryl) mg medother_diphen <input type="checkbox"/> Droperidol (Inapsine) mg medother_drop <input type="checkbox"/> Etomidate (Amidate) mg medother_etom <input type="checkbox"/> Flumazenil (Romazicon) mg medother_flum <input type="checkbox"/> Haloperidol (Haldol) mg medother_halo <input type="checkbox"/> Hydromorphone (Dilaudid) mg medother_hydromor <input type="checkbox"/> Hydroxyzine (Atarx, Vistaril) mg medother_hydroxyz <input type="checkbox"/> Ibuprofen (Advil, Motrin) mg medother_ibu <input type="checkbox"/> Ketamine (Ketalar) mg medother_ket <input type="checkbox"/> Ketorolac (Toradol) mg medother_ketoro <input type="checkbox"/> Melatonin mg medother_mel <input type="checkbox"/> Meperidine (Demerol) mg medother_mep <input type="checkbox"/> Nalbuphine Hydrochloride (Nubain) mg medother_nalbu <input type="checkbox"/> Naloxone Hydrochloride (Narcan) mg medother_nalox <input type="checkbox"/> Olanzapine (Zyprexa) mg medother_olanz <input type="checkbox"/> Oxycodone immediate release (Oxycontin) mg medother_oxycodir <input type="checkbox"/> Oxycodone sustained release (Oxycontin) mg medother_oxycodsr <input type="checkbox"/> Pentobarbital (Nembutal) mg medother_pento <input type="checkbox"/> Pentothal sodium (Thiopental) mg medother_pentothal <input type="checkbox"/> Phenobarbital (Luminal) mg medother_pheno

- Propofol (Diprivan) mcg **medother_prop**
- Risperidone (Risperdal) mg **medother_risp**
- Sufentanil (Sufenta) mcg **medother_suf**
- Sweet-Ease (oral sucrose) *(dose not required) **medother_sweetease**
- Zolpidem (Ambien) mg **medother_zol**
- Any inhalation anesthetic *(dose not required) **medother_inhalan**
- Other **medother_other**

If
Other, ~~medotheroth~~
specify:

Note: Removed (not applicable)

No (0)

RESTORE: Form 4b: PICU_Neuro

Form 4b: PICU_Neuro

1. Pupillary response (closest to 08:00)	<input type="radio"/> Both reactive (1) pup <input type="radio"/> One nonreactive (> 3 mm) (2) <input type="radio"/> Both nonreactive (> 3 mm) (3)
2. Glasgow Coma Score (closest to 08:00)	Eye opening: gcseye <input type="radio"/> (4) Spontaneous <input type="radio"/> (3) To speech <input type="radio"/> (2) To pain <input type="radio"/> (1) None <input type="radio"/> Not done (0) Best verbal (if patient intubated, give best estimate): gcsverbal <input type="radio"/> (5) Oriented/smiles, fixes and follows <input type="radio"/> (4) Confused conversation/irritable cries <input type="radio"/> (3) Inappropriate words/cries to pain <input type="radio"/> (2) Incomprehensible sounds/moans to pain <input type="radio"/> (1) None <input type="radio"/> Not done (0) Best motor response: gcsmotor <input type="radio"/> (6) Obeys commands, normal spontaneous movement <input type="radio"/> (5) Localizes/withdraws to touch <input type="radio"/> (4) Withdraws to pain <input type="radio"/> (3) Decorticate-abnormal flexion <input type="radio"/> (2) Decerebrate-abnormal extension <input type="radio"/> (1) None <input type="radio"/> Not done (0)
3. Worst level of consciousness (closest to 08:00)	<input type="radio"/> Normal (1) consc <input type="radio"/> Lethargy: Arousable with stimulation to a state capable of communication, associated with an acute process (2) <input type="radio"/> Stupor: Arousable with vigorous and repeated stimulation to withdraw and/or moaning, associated with an acute process (3) <input type="radio"/> Coma: Nonpurposeful, or no response to vigorous stimulation, associated with an acute process(4) <input type="radio"/> Not assessed (5) <input type="radio"/> None of the above - chronic altered mental status, no change from the patient's baseline (6)

4. Were any of the following neurological tests performed on this study day?

Brain CT: **brainct**

Yes (1)

No(0)

Brain MRI: **brainmri**

Yes (1)

No(0)

Lumbar puncture: **lumbar**

Yes (1)

No(0)

RESTORE: Form 4b: PICU_Resp_Labs

Section: Respiratory Support

1.	Was there assisted breathing on this study day? If No, skip to "Respiratory Assessments" section. For questions 2 through 6, number of hours/day should add up to number of hours on DOV tab.	<input type="radio"/> Yes (1) astbr <input type="radio"/> No (0)	
Note: A value of Yes and 0 indicates 29 minutes or less			
2.	None	<input type="radio"/> Yes, # hours/day: 0-24 (1) nonehr <input type="radio"/> No (0)	none
3.	CPAP \geq 5 cm H ₂ O	<input type="radio"/> Yes, # hours/day: 0-24 (1) cpaphr <input type="radio"/> No (0)	cpap
4.	Humidified High Flow Nasal Cannula (HHFNC \geq 5 L/min of Oxygen flow)	<input type="radio"/> Yes, # hours/day: 0-24 (1) hhfnchr <input type="radio"/> No (0)	hhfnc
5.	BiPAP	<input type="radio"/> Yes, # hours/day: 0-24 (1) bipaphr <input type="radio"/> No (0)	bipap
6.	Ventilator If No, skip to "Respiratory Assessments" section. For questions 8 through 11, number of hours/day should add up to # hours/day recorded in question 6.	<input type="radio"/> Yes, # hours/day: 0-24 (1) venthr <input type="radio"/> No (0)	vent
7.	If on ventilator, was the patient spontaneously breathing at the time of ERT assessment or at 08:00?	<input type="radio"/> Yes (1) spontbr08 <input type="radio"/> No (0)	
8.	Ventilator mode: Spontaneous without a set back up rate	<input type="radio"/> Yes, # hours/day: 0-24 (1) sponworatehr <input type="radio"/> No (0)	sponworate
9.	Ventilator mode: Spontaneous with a set back up rate	<input type="radio"/> Yes, # hours/day: 0-24 (1) sponwratehr <input type="radio"/> No (0)	sponwrate
10.	Ventilator mode: Controlled only (no spontaneous breathing)	<input type="radio"/> Yes, # hours/day: 0-24 (1) controlmodehr <input type="radio"/> No (0)	controlmode
11.	Ventilator mode: HFOV	<input type="radio"/> Yes, # hours/day: 0-24 (1) hfovhr <input type="radio"/> No (0)	hfov

Section: Respiratory Assessments

For questions 12 through 15, record values that were measured simultaneously closest to 08:00.

12.	PaO ₂	<input type="text" value="pao2"/> mmHg <input type="checkbox"/> No arterial specimen <input type="checkbox"/> On ECMO <input type="text" value="pao2ecmo"/> <input type="text" value="pao2nospec"/>
13.	Mean airway pressure	<input type="text" value="map"/> cm H ₂ O <input type="checkbox"/> No airway pressure <input type="checkbox"/> On ECMO <input type="text" value="mapecmo"/> <input type="text" value="mapnopres"/>
14.	FiO ₂	<input type="text" value="fio2"/> <input type="checkbox"/> Not on assisted breathing <input type="text" value="fio2notab"/>
15.	SpO ₂ (pulse oximetry)	<input type="text" value="spo2"/> %
16.	Was a chest x-ray obtained on this study day?	<input type="radio"/> Yes (1) <input type="text" value="respixray"/> If Yes, is this the first study day that <u>new</u> bilateral infiltrates/opacities were identified? <input type="radio"/> Yes (1) <input type="text" value="respbilat"/> <input type="radio"/> No (0) <input type="radio"/> No (0)
17.	Is this patient showing evidence of left atrial (LA) hypertension (e.g., ECHO+) on this study day?	<input type="radio"/> Yes (1) <input type="radio"/> No (0) <input type="text" value="resplah"/>

Section: Extubation Status

18.	Was this patient intubated or did this patient remain intubated this study day? If No, skip to "Labs" section.	<input type="radio"/> Yes (1) <input type="text" value="intub"/> If Yes, does patient have ETT air leak on this study day? <input type="text" value="airleak"/> <input type="radio"/> Yes (1) <input type="radio"/> No (0) <input type="radio"/> Not measured (2) <input type="radio"/> No (0)
19.	Was an Extubation Readiness Test (ERT) done on this study day? If Yes, complete a Form 6b for each ERT.	<input type="radio"/> Yes (1) <input type="text" value="ertdone"/> If Yes, how many ERTs were performed on this study day? <input type="text" value="ertno"/> <input type="radio"/> No (0)
20.	Was this patient extubated on this study day? If Yes, "Add entry" for each extubation this study day. If No, skip to "Labs" section.	<input type="radio"/> Yes (1) <input type="radio"/> No (0) <input type="text" value="extub"/>

Section: Extubation Status Entry

21.1	Extubation time	<input type="text"/> : <input type="text"/> 24-hour clock Note: Changed to hours since intubation extub_hrssinceintub1, extub_hrssinceintub2
21.2	Extubation type If unplanned extubation, complete a Form 9: Adverse Events.	<input type="radio"/> Planned (passed ERT) (1) <input type="radio"/> Planned (no ERT or failed ERT) (2) extubtype1, extubtype2 <input type="radio"/> Unplanned extubation without soft restraints (3) <input type="radio"/> Unplanned extubation with soft restraints (4)
21.3	If an unplanned extubation, did it occur during an arousal assessment?	<input type="radio"/> Yes (1) <input type="radio"/> No (0) unplextubaa1, unplextubaa2 <input type="radio"/> N/A Extubation was planned (2)
21.4	Reintubated within 24 hours? If reintubated, complete a Form 9: Adverse Events.	<input type="radio"/> Yes (1) reintub1, reintub2 If Yes, reintubation date and time: Note: Changed to hours since extubation <input type="text"/> / <input type="text"/> / <input type="text"/> reintub_hrssinceextub1, reintub_hrssinceextub2 <input type="text"/> : <input type="text"/> 24-hour clock Reason patient was reintubated: reintubcode1, reintubcode2 <input type="radio"/> Upper airway - stridor, hypoxia/hypercarbia (1) <input type="radio"/> Lower respiratory - hypoxia/hypercarbia (2) <input type="radio"/> Insufficient respiratory effort due to over sedation (3) <input type="radio"/> Insufficient respiratory effort due to neuromuscular fatigue (4) <input type="radio"/> Insufficient respiratory effort due to neurologic status (5) <input type="radio"/> Planned surgery or other procedure requiring deep sedation (6) <input type="radio"/> Excessive secretions that could not be adequately cleared (7) <input type="radio"/> ETT size/ETT location change (8) <input type="radio"/> Other, (99) reintubcodeoth1, reintubcodeoth2 specify: <input type="radio"/> No (0)

Section: Labs

If obtained more than once, record results closest to 08:00. If test not done, check the "Not Done" box.

22.	BUN	bun mg/dL <input type="checkbox"/> Not Done bunndlabs
23.	Creatinine	creat mg/dL <input type="checkbox"/> Not Done creatndlabs
24.	ALT	alt U/L <input type="checkbox"/> Not Done altndlabs
25.	Total Bilirubin	bilitot mg/dL <input type="checkbox"/> Not Done bilitotndlabs
26.	Direct Bilirubin	bilidirect mg/dL <input type="checkbox"/> Not Done bilidirndlabs
27.	Prothrombin Time (PT)	<input type="text"/> pt sec <input type="checkbox"/> Not Done ptndlabs

28.	Albumin	alb	g/dL	<input type="checkbox"/> Not Done	albndlabs
29.	Total Protein	totprot	g/dL	<input type="checkbox"/> Not Done	totprondlabs
30.	White Blood Count	wbc	K/ μ L	<input type="checkbox"/> Not Done	wbcndlabs
31.	Platelet count	plate	K/ μ L	<input type="checkbox"/> Not Done	platendlabs

RESTORE: Form 4b: PICU_Misc

Section: Miscellaneous

1.	Any vasoactive medications	<input type="radio"/> None (1) <input type="radio"/> Single (2) <input type="radio"/> Multiple (3)	vasoactive
2.	Any dialysis technique	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	dialysis
3.	Any supplemental oxygen (any delivery device)	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	supplo2
4.	ICU-only interventions (e.g., ECMO cannulation, pacemaker, cardioversion, endoscopy, emergency operation, gastric lavage) Note: Routine interventions such as x-rays, echocardiography, electrocardiography, dressings, and venous or arterial line are not included.	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	icuint
5.	Patient escorted outside the ICU for any intervention (e.g., surgery, diagnostic procedure)	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	outicuint
6.	Devices <u>this study day</u>	Arterial line: art <input type="radio"/> Existing(1) <input type="radio"/> New(2) <input type="radio"/> None (0) Central venous line: cvl <input type="radio"/> Existing(1) <input type="radio"/> New(2) <input type="radio"/> None (0) Peripheral IV: pvl <input type="radio"/> Existing(1) <input type="radio"/> New(2) <input type="radio"/> None (0) Nasogastric tube: ngtube <input type="radio"/> Existing(1) <input type="radio"/> New(2) <input type="radio"/> None (0) Bladder catheter: bladcath <input type="radio"/> Existing(1) <input type="radio"/> New(2) <input type="radio"/> None (0) Chest tube: chesttube <input type="radio"/> Existing(1) <input type="radio"/> New(2) <input type="radio"/> None (0) Surgical wound drain: wounddrain <input type="radio"/> Existing(1) <input type="radio"/> New(2) <input type="radio"/> None (0)	

Section: Event Log

7.	Identify all events that occurred <u>this study day</u> (check all that apply):	<input type="checkbox"/> Inadequate pain management eventlog_ipm <input type="checkbox"/> Inadequate sedation management eventlog_ism
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If any event, complete a Form 9: Adverse Events form.

- Clinically significant iatrogenic withdrawal **eventlog_csiw**
- Unplanned ETT extubation **eventlog_selfextub**
- Post extubation stridor with chest-wall retractions at rest **eventlog_stridor**
- Extubation failure - reintubation within 24 hours **eventlog_extubfail**
- Unplanned removal of arterial access **eventlog_art**
- Unplanned removal of central venous access **eventlog_cvl**
- Unplanned removal of peripheral venous access **eventlog_pvl**
- Unplanned removal of nasogastric drainage tube **eventlog_ngtube**
- Unplanned removal of bladder catheter **Note: Responses of unplanned removal of bladder catheter, chest tube, and other tube were collapsed to other tube**
- Unplanned removal of chest tube **Note: Removed for duplicity (see Form 9)**
- Unplanned removal of "other" tube, specify: ~~eventothtube~~ **eventlog_othtube**
- Ventilator-associated pneumonia (new this study day) **eventlog_vap**
- Catheter-associated bloodstream infection (new this study day) **eventlog_cabsi**
- Stage 2+ pressure ulcers (new this study day) **eventlog_ulcer**
- Tracheostomy (new this study day) **eventlog_trach**
- Other, specify: ~~eventoth~~ **eventlog_othevent** **Note: Removed for duplicity (see Form 9)**
- None **eventlog_noevent**

Section: Patient Status

8. Was a WAT-1 performed on this study day?

- Yes - **Complete Form 7.**(1) **wat**
- No(0)

9. Has the patient been discharged from the *RESTORE* study on this study day?

- Yes - **No further daily forms are needed. Proceed to Form 8.** (1) **studydis**
- If Yes, specify reason for study discharge:
- Pulldown list 4 **studydisreas**
- No(0)

Data should reflect 24-hour period (00:00 - 23:59).

Section: Pain Scores

- | | | | |
|----|---|---|---|
| 1. | Pain assessment tool used closest to <u>08:00</u> | <input type="radio"/> FLACC (1)
<input type="radio"/> FACES (2)
<input type="radio"/> NRS/VAS (3)
<input type="radio"/> Individualized NRS (4)
<input type="radio"/> Other, (99) specify: | paintool

paintooloth |
| 2. | Pain score closest to <u>08:00</u> | 0-10 <input type="text"/> | pain8 |

Section: Comfort Medications - Narcotics

- | | | | |
|----|--|---|--------------|
| 3. | Did the patient receive narcotics on this study day?

If No, skip to "Comfort Medications - Benzodiazepines" section. | <input type="radio"/> Yes (1)
<input type="radio"/> No (0) | narc |
| 4. | Total combined morphine this study day

Note: 24-hour dose calculation tool on <i>RESTORE</i> study website. | morphtot | mg/24 hours |
| 5. | Total combined fentanyl this study day | fenttot | mcg/24 hours |
| 6. | Total combined methadone this study day | methtot | mg/24 hours |

Section: Comfort Medications - Benzodiazepines

- | | | | |
|----|--|---|-------------|
| 7. | Did the patient receive benzodiazepines on this study day?

If No, skip to "Other Comfort Medications" section. | <input type="radio"/> Yes (1)
<input type="radio"/> No (0) | benz |
| 8. | Total combined midazolam this study day | midaztot | mg/24 hours |
| 9. | Total combined lorazepam this study day | loraztot | mg/24 hours |

Section: Other Comfort Medications

- | | | | |
|-----|---|---|----------------|
| 10. | Did the patient receive other comfort medications on this study day?

If Yes, "Add entry" for each other comfort medication. | <input type="radio"/> Yes (1)
<input type="radio"/> No (0) | comfmed |
|-----|---|---|----------------|

Other Comfort Medications Entry

11.1	Select the other comfort medication	<input type="button" value="v"/> Pulldown list 3 comfmedcode1, ..., comfmedcode4
11.2	If Other, specify	comfmedoth1, ..., comfmedoth4
11.3	Total 24-hour dose of this other comfort medication	<input type="radio"/> mg/24 hours <input type="radio"/> mcg/24 hours (2) comfmedtot_unit1, ..., comfmedtot_unit4 comfmedtot1, ..., comfmedtot4 (1)

Section: Medications for Other Reasons

12.	Did the patient receive any medications to facilitate sleep on this study day?	<input type="radio"/> Yes, select the medication: <input type="button" value="v"/> Pulldown list 3 sleepmedcode (1) sleepmed If sleepmedoth Other, specify: Total 24-hour dose of this sleep agent: sleepmedtot <input type="radio"/> mg/24 hours <input type="radio"/> mcg/24 hours (2) sleepmedtot_unit (1) <input type="radio"/> No (0)
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13.	Did patient receive any medications to manage delirium on this study day?	<input type="radio"/> Yes, select the medication: <input type="button" value="v"/> Pulldown list 3 delmedcode (1) delmed If delmedoth Other, specify: Total 24-hour dose of this delirium agent: delmedtot <input type="radio"/> mg/24 hours <input type="radio"/> mcg/24 hours (2) delmedtot_unit (1) <input type="radio"/> No (0)
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14.	Did the patient receive any of these medications for any other reason on this study day?	<input type="radio"/> Yes (1) medother Select the medication(s): <input type="checkbox"/> Acetaminophen (Tylenol) mg medother_acetam <input type="checkbox"/> Tylenol with codeine mg medother_tylcod <input type="checkbox"/> Chloral Hydrate (Aquachloral) mg medother_ch <input type="checkbox"/> Clonazepam (Klonopin) mg medother_clonaz <input type="checkbox"/> Clonidine (Catapres) mcg medother_clon <input type="checkbox"/> Codeine mg medother_cod <input type="checkbox"/> Dexmedetomidine (Precedex) mcg medother_dex <input type="checkbox"/> Diazepam (Valium) mg medother_diaz <input type="checkbox"/> Diphenhydramine (Benadryl) mg medother_diphen <input type="checkbox"/> Droperidol (Inapsine) mg medother_drop <input type="checkbox"/> Etomidate (Amidate) mg medother_etom <input type="checkbox"/> Flumazenil (Romazicon) mg medother_flum <input type="checkbox"/> Haloperidol (Haldol) mg medother_halo
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- Hydromorphone (Dilaudid) mg **medother_hydromor**
- Hydroxyzine (Atarx, Vistaril) mg **medother_hydroxyz**
- Ibuprofen (Advil, Motrin) mg **medother_ibu**
- Ketamine (Ketalar) mg **medother_ket**
- Ketorolac (Toradol) mg **medother_ketoro**
- Melatonin mg **medother_mel**
- Meperidine (Demerol) mg **medother_mep**
- Nalbuphine Hydrochloride (Nubain) mg **medother_nalbu**
- Naloxone Hydrochloride (Narcan) mg **medother_nalox**
- Olanzapine (Zyprexa) mg **medother_olanz**
- Oxycodone immediate release (Oxycontin) mg **medother_oxycodir**
- Oxycodone sustained release (Oxycontin) mg **medother_oxycodsr**
- Pentobarbital (Nembutal) mg **medother_pento**
- Pentothal sodium (Thiopental) mg **medother_pentothal**
- Phenobarbital (Luminal) mg **medother_pheno**
- Propofol (Diprivan) mcg **medother_prop**
- Risperidone (Risperdal) mg **medother_risp**
- Sufentanil (Sufenta) mcg **medother_suf**
- Sweet-Ease (oral sucrose) *(dose not required) **medother_sweetease**
- Zolpidem (Ambien) mg **medother_zol**
- Any inhalation anesthetic *(dose not required) **medother_inhalan**
- Other **medother_other**

If
Other,
specify:

medotheroth	Note: Removed (not applicable)
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No (0)

RESTORE: Form 5a: Ward_Neuro

Form 5a: Ward_Neuro

1. Pupillary response (closest to 08:00)	<input type="radio"/> Both reactive (1) <input type="radio"/> One nonreactive (> 3 mm) (2) pup <input type="radio"/> Both nonreactive (> 3 mm) (3)
2. Worst level of consciousness (closest to 08:00)	<input type="radio"/> Normal (1) consc <input type="radio"/> Lethargy: Arousable with stimulation to a state capable of communication, associated with an acute process (2) <input type="radio"/> Stupor: Arousable with vigorous and repeated stimulation to withdraw and/or moaning, associated with an acute process (3) <input type="radio"/> Coma: Nonpurposeful, or no response to vigorous stimulation, associated with an acute process (4) <input type="radio"/> Not assessed (5) <input type="radio"/> None of the above - chronic altered mental status, no change from the patient's baseline (6)


RESTORE: Form 5a: Ward_Misc

Form 5a: Ward_Misc

1. Was a WAT-1 performed on this study day?	<input type="radio"/> Yes - Complete Form 7. (1) wat <input type="radio"/> No (0)
2. Was the patient transferred back to the PICU?	<input type="radio"/> Yes (1) bounceback If Yes, was the transfer required for continued management of the same clinical problem and/or related to the use/weaning of sedation? bouncebackreas <input type="radio"/> Yes - Restart daily PICU forms. (1) <ul style="list-style-type: none"><input type="radio"/> Same clinical problem (1) bouncebackreas2<input type="radio"/> Related to use/weaning of sedation (2)<input type="radio"/> Both (3) <input type="radio"/> No (0) <input type="radio"/> No (0)
3. Has the patient been discharged from the <i>RESTORE</i> study on this study day?	<input type="radio"/> Yes - No further daily forms are needed. Proceed to Form 8. (1) studydis If Yes, specify reason for study discharge: <input type="text" value="Pulldown list 4"/> studydisreas <input type="radio"/> No (0)

Data should reflect 24-hour period (00:00 - 23:59).

Section: Weaning

1.	Was the <i>RESTORE</i> weaning plan followed this study day?	<input type="radio"/> Yes (1) <input type="radio"/> No (0) <input type="radio"/> Plan never provided (2)	weanplan
		If plan never provided, skip to "Pain Scores" section.	
2.	Were narcotics weaned per protocol on this study day?	<input type="radio"/> Yes (1) <input type="radio"/> No (0) <input type="radio"/> N/A (narcotic wean complete) (2)	weannarc
3.	Were benzodiazepines weaned per protocol on this study day?	<input type="radio"/> Yes (1) <input type="radio"/> No (0) <input type="radio"/> N/A (Bz wean complete) (2)	weanbenz
4.	Were narcotics and benzodiazepines weaned at the same time during this study day?	<input type="radio"/> Yes (1) <input type="radio"/> No (0) <input type="radio"/> N/A (narcotic or Bz wean complete) (2)	weansame
5.	Was a maximum WAT-1 score identified on this study day? If No, skip over next question.	<input type="radio"/> Yes (1) If Yes, what was the maximum WAT-1 score? maxwat1 <input type="text" value="0-12"/>  <input type="radio"/> No (0)	weanmaxwat1
6.	Did the patient score higher than the maximum WAT-1 score on this study day?	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	weanhighwat
7.	Was clonidine administered this study day?	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	weanclonidine
8.	Was methadone administered this study day?	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	weanmethadone

Section: Pain Scores

9.	Pain assessment tool used closest to <u>08:00</u>	<input type="radio"/> FLACC (1) <input type="radio"/> FACES (2) <input type="radio"/> NRS/VAS (3) <input type="radio"/> Individualized NRS (4) <input type="radio"/> Other, (99) specify:	paintool paintooloth
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10.	Pain score closest to <u>08:00</u>	0-10	pain8
Section: Comfort Medications - Narcotics			
11.	Did the patient receive narcotics on this study day? If No, skip to "Comfort Medications - Benzodiazepines" section.	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	narc
12.	Total combined morphine this study day Note: 24-hour dose calculation tool on <i>RESTORE</i> study website.	morphtot mg/24 hours	
13.	Total combined fentanyl this study day	fenttot mcg/24 hours	
14.	Total combined methadone this study day	methtot mg/24 hours	
Section: Comfort Medications - Benzodiazepines			
15.	Did the patient receive benzodiazepines on this study day? If No, skip to "Other Comfort Medications" section.	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	benz
16.	Total combined midazolam this study day	midaztot mg/24 hours	
17.	Total combined lorazepam this study day	loraztot mg/24 hours	
Section: Other Comfort Medications			
18.	Did the patient receive other comfort medications on this study day? If Yes, "Add entry" for each other comfort medication.	<input type="radio"/> Yes (1) <input type="radio"/> No (0)	comfmed
Other Comfort Medications Entry			
19.1	Select the other comfort medication	Pulldown list 3	comfmedcode1, ..., comfmedcode6
19.2	If Other, specify		comfmedoth1, ..., comfmedoth6
19.3	Total 24-hour dose of this other comfort medication	<input type="radio"/> mg/24 hours (1) <input type="radio"/> mcg/24 hours (2)	comfmedtot_unit1, ..., comfmedtot_unit6
Section: Medications for Other Reasons			
20.	Did the patient receive any medications to	<input type="radio"/> Yes, select the medication: (1)	Pulldown list 3 sleepmedcode

	facilitate sleep on this study day?	<p>If sleepmedoth Other, specify:</p> <p>Total 24-hour dose of this sleep agent: sleepmedtot <input type="radio"/> mg/24 hours <input type="radio"/> mcg/24 hours (2) sleepmedtot_unit (1)</p> <p><input type="radio"/> No (0)</p>
21.	Did patient receive any medications to manage delirium on this study day?	<p><input type="radio"/> Yes, select the medication: <input type="button" value="v"/> Pulldown list 3 delmedcode (1) delmed</p> <p>If delmedoth Other, specify:</p> <p>Total 24-hour dose of this delirium agent: delmedtot <input type="radio"/> mg/24 hours <input type="radio"/> mcg/24 hours (2) delmedtot_unit (1)</p> <p><input type="radio"/> No (0)</p>
22.	Did the patient receive any of these medications for any other reason on this study day?	<p><input type="radio"/> Yes (1) medother</p> <p>Select the medication(s):</p> <ul style="list-style-type: none"> <input type="checkbox"/> Acetaminophen (Tylenol) mg medother_acetam <input type="checkbox"/> Tylenol with codeine mg medother_tylcod <input type="checkbox"/> Chloral Hydrate (Aquachloral) mg medother_ch <input type="checkbox"/> Clonazepam (Klonopin) mg medother_clonaz <input type="checkbox"/> Clonidine (Catapres) mcg medother_clon <input type="checkbox"/> Codeine mg medother_cod <input type="checkbox"/> Dexmedetomidine (Precedex) mcg medother_dex <input type="checkbox"/> Diazepam (Valium) mg medother_diaz <input type="checkbox"/> Diphenhydramine (Benadryl) mg medother_diphen <input type="checkbox"/> Droperidol (Inapsine) mg medother_drop <input type="checkbox"/> Etomidate (Amidate) mg medother_etom <input type="checkbox"/> Flumazenil (Romazicon) mg medother_flum <input type="checkbox"/> Haloperidol (Haldol) mg medother_halo <input type="checkbox"/> Hydromorphone (Dilaudid) mg medother_hydromor <input type="checkbox"/> Hydroxyzine (Atarx, Vistaril) mg medother_hydroxyz <input type="checkbox"/> Ibuprofen (Advil, Motrin) mg medother_ibu <input type="checkbox"/> Ketamine (Ketalar) mg medother_ket <input type="checkbox"/> Ketorolac (Toradol) mg medother_ketoro <input type="checkbox"/> Melatonin mg medother_mel <input type="checkbox"/> Meperidine (Demerol) mg medother_mep <input type="checkbox"/> Nalbuphine Hydrochloride (Nubain) mg medother_nalbu <input type="checkbox"/> Naloxone Hydrochloride (Narcan) mg medother_nalox <input type="checkbox"/> Olanzapine (Zyprexa) mg medother_olanz

- Oxycodone immediate release (Oxycontin) mg [medother_oxycodir](#)
- Oxycodone sustained release (Oxycontin) mg [medother_oxycodsr](#)
- Pentobarbital (Nembutal) mg [medother_pento](#)
- Pentothal sodium (Thiopental) mg [medother_pentothal](#)
- Phenobarbital (Luminal) mg [medother_pheno](#)
- Propofol (Diprivan) mcg [medother_prop](#)
- Risperidone (Risperdal) mg [medother_risp](#)
- Sufentanil (Sufenta) mcg [medother_suf](#)
- Sweet-Ease (oral sucrose) *(dose not required) [medother_sweetease](#)
- Zolpidem (Ambien) mg [medother_zol](#)
- Any inhalation anesthetic *(dose not required) [medother_inhalan](#)
- Other [medother_other](#)

If ~~[medotherotr](#)~~
Other,
specify:

Note: Removed (not applicable)

No (0)

RESTORE: Form 5b: Ward_Neuro

Form 5b: Ward_Neuro

1. Pupillary response (closest to 08:00)	<input type="radio"/> Both reactive (1) <input type="radio"/> One nonreactive (> 3 mm) (2) pup <input type="radio"/> Both nonreactive (> 3 mm)(3)
2. Worst level of consciousness (closest to 08:00)	<input type="radio"/> Normal (1) consc <input type="radio"/> Lethargy: Arousable with stimulation to a state capable of communication, associated with an acute process (2) <input type="radio"/> Stupor: Arousable with vigorous and repeated stimulation to withdraw and/or moaning, associated with an acute process (3) <input type="radio"/> Coma: Nonpurposeful, or no response to vigorous stimulation, associated with an acute process (4) <input type="radio"/> Not assessed (5) <input type="radio"/> None of the above - chronic altered mental status, no change from the patient's baseline (6)

RESTORE: Form 5b: Ward_Misc

Form 5b: Ward_Misc

1. Was a WAT-1 performed on this study day?	<input type="radio"/> Yes - Complete Form 7. (1) wat <input type="radio"/> No (0)
2. Was the patient transferred back to the PICU?	<input type="radio"/> Yes (1) bounceback If Yes, was the transfer required for continued management of the same clinical problem and/or related to the use/weaning of sedation? bouncebackreas <input type="radio"/> Yes - Restart daily PICU forms. (1) bouncebackreas2 <input type="radio"/> Same clinical problem (1) <input type="radio"/> Related to use/weaning of sedation (2) <input type="radio"/> Both (3) <input type="radio"/> No (0) <input type="radio"/> No (0)
3. Has the patient been discharged from the <i>RESTORE</i> study on this study day?	<input type="radio"/> Yes - No further daily forms are needed. Proceed to Form 8. (1) studydis If Yes, specify reason for study discharge: <input type="text" value="Pull down list 4"/> studydisreas <input type="radio"/> No (0)

Section: Extubation Readiness

1. Time of ERT	<input type="text"/> : <input type="text"/> 24-hour clock ert_hrssinceintub Note: Changed to hours since intubation
2. Is this ERT a retest after a sedation wean?	<input type="radio"/> Yes (1) retest <input type="radio"/> No (0)
3. What was the SBS score at the start of the ERT?	<input type="text"/> -3, -2, -1, 0, 1, 2 ertsbsstart
4. What was the SBS score at the end of the ERT?	<input type="text"/> -3, -2, -1, 0, 1, 2 ertsbsend
5. Did the patient pass the extubation readiness test? If No and reason(s) specified, STOP. End of form.	<input type="radio"/> Yes (1) ertpass <input type="radio"/> No (0) If No, specify the reason(s) for <u>not passing</u> the extubation readiness test (check all that apply): <ul style="list-style-type: none"> <input type="checkbox"/> SpO₂ < 95% ertfail_spo2 <input type="checkbox"/> Exhaled tidal volume < 5 ml/kg ertfail_tv <input type="checkbox"/> Respiratory rate above goal for age (breaths per minute) ertfail_rr <ul style="list-style-type: none"> ● < 6 months: 20 - 60 ● 6 months - 2 years: 15 - 45 ● 2 - 5 years: 15 - 40 ● > 5 years: 10 - 35
6. Was the patient extubated within 6 hours of passing ERT?	<input type="radio"/> Yes (1) extub6ert <input type="radio"/> No (0) If No, specify the reason(s) the patient was not extubated within 6 hours of passing test (check all that apply): <ul style="list-style-type: none"> <input type="checkbox"/> No ETT leak notextubreas_noleak <input type="checkbox"/> Insufficient respiratory effort due to over sedation notextubreas_oversed <input type="checkbox"/> Insufficient respiratory effort due to questionable neurological status notextubreas_neurolog <input type="checkbox"/> Insufficient respiratory effort due to questionable neuromuscular status notextubreas_neuromus <input type="checkbox"/> Planned procedure required deep sedation notextubreas_procsed <input type="checkbox"/> Planned surgical procedure in operating room notextubreas_procor <input type="checkbox"/> Excessive secretions notextubreas_secret <input type="checkbox"/> Other, notextubreas_oth notextubothreas specify:

Note: notextubothreas has been recategorized for ease of use

Section: WAT-1 Assessment

1.	How many times was WAT-1 completed on this study day?	<input type="text" value="watno"/>
2.	Highest WAT-1 on this study day Complete the information below for the HIGHEST WAT-1 on this study day.	0-12 <input type="text" value="wathi"/>
3.	Time of the highest WAT-1 on this study day	<input type="text" value=""/> : <input type="text" value=""/> 24-hour clock Note: Removed (not relevant)

Section: WAT-1 Information from Patient's Record (Previous 12 Hours)

4.	Any loose or watery stools	<input type="radio"/> (1) Yes <input type="radio"/> (0) No	stool
5.	Any vomiting, wretching, or gagging	<input type="radio"/> (1) Yes <input type="radio"/> (0) No	vomit
6.	Temperature often > 37.8 C	<input type="radio"/> (1) Yes <input type="radio"/> (0) No	wattemp

Section: 2 Minute Pre-stimulus Observation

7.	State Behavior	<input type="radio"/> (1) Awake distressed or SBS \geq 1 <input type="radio"/> (0) Asleep/awake calm or SBS \leq 0	stbehav
8.	Tremor	<input type="radio"/> (1) Moderate/severe <input type="radio"/> (0) None/mild	tremor
9.	Sweating	<input type="radio"/> (1) Yes <input type="radio"/> (0) No	sweat
10.	Uncoordinated/repetitive movements	<input type="radio"/> (1) Moderate/severe <input type="radio"/> (0) None/mild	move
11.	Yawning/sneezing	<input type="radio"/> (1) More than 2 <input type="radio"/> (0) None or 1	yawn

Section: 1 Minute Stimulus Observation

12.	Startle to touch	<input type="radio"/> (1) Moderate/severe <input type="radio"/> (0) None/mild	startle
13.	Muscle tone	<input type="radio"/> (1) Increased <input type="radio"/> (0) Normal	muscle

Section: Post-stimulus

14. Time to gain calm state ($SBS \leq 0$)

- (2) > 5 min
- (1) 2 - 5 min
- (0) < 2 min

timetocalm

RESTORE: Form 8: Discharge Form fm08

Section: Patient Termination

Note: All dates have been reformulated to be days since study day 0

1.	Was the patient withdrawn early from the study?	<input type="radio"/> Yes, date withdrawn: <input type="text" value=""/> / <input type="text" value=""/> / <input type="text" value=""/> withdraw_dayssince day0 (1) withdraw Reason patient was withdrawn early: withdrawreas <input type="radio"/> Readmitted to the PICU for a new problem (1) <input type="radio"/> Redirection of care (2) <input type="radio"/> Withdrawal of consent - Data should not be collected after withdrawal of consent. (3) <input type="radio"/> Other, (99) withdrawreaso oth Note: withdrawreaso has been recategorized for ease of use specify: <input type="radio"/> No (0)
2.	Did the patient develop any exclusion criterion after enrollment?	<input type="radio"/> Yes (1) devexcl yn Select exclusion criterion: devexcl <input type="radio"/> Critical airway(1) <input type="radio"/> Placed on PCA(2) <input type="radio"/> Neuromuscular failure (3) <input type="radio"/> Care considered futile (4) <input type="radio"/> Other, (99) devexcl oth ————— Note: Removed to deidentify data specify: Date/time criterion developed: devexcl_dayssince day0 <input type="text" value=""/> / <input type="text" value=""/> / <input type="text" value=""/> <input type="text" value=""/> : <input type="text" value=""/> 24-hour clock <input type="radio"/> No (0)
3.	Was the primary goal of comfort management ever changed from "Management of intubation/mechanical ventilation or weaning from medications used to manage intubation/ventilation" to the use of opioids or Bz for other purposes (e.g., continued pain management for pre-existing conditions, wound care only, seizures, etc.)?	<input type="radio"/> Yes (1) medgoalchange If Yes, date: <input type="text" value=""/> / <input type="text" value=""/> / <input type="text" value=""/> medgoalchange_dayssince day0 Rationale for continued opioid or benzodiazepine use: medgoalchangereas Note: medgoalchangereas has been recategorized for ease of use <input type="radio"/> No (0)

Section: Date Verification

4.	Date and time of successful endotracheal extubation (Successful = patient remained extubated for at least 24 consecutive hours) If patient not extubated for at least 24 consecutive hours, select	Date and time: <input type="text" value=""/> / <input type="text" value=""/> / <input type="text" value=""/> extub_dayssince day0 <input type="text" value=""/> : <input type="text" value=""/> 24-hour clock N/A: <input type="checkbox"/> Patient discharged with tracheostomy naextub_trach
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	FYUgcb(s).	<input type="checkbox"/> Patient still intubated on transfer to another ICU naextub_transfer <input type="checkbox"/> Patient died by Study Day 90 naextub_death <input type="checkbox"/> Patient still intubated on Study Day 90 naextub_day90
5.	Date and time assisted breathing discontinued for at least 24 consecutive hours (includes any amount of time on mechanical ventilation, BiPAP, Humidified High Flow Nasal Cannula (HHFNC \geq 5 L/min of Oxygen flow), or CPAP \geq 5 cm H ₂ O) If assisted breathing not discontinued for at least 24 consecutive hours, select reason(s).	Date and time: astbrend_dayssince day0 <input type="text"/> / <input type="text"/> / <input type="text"/> <input type="text"/> : <input type="text"/> 24-hour clock N/A: <input type="checkbox"/> Patient still on assisted breathing on hospital discharge naastbrend_dis <input type="checkbox"/> Patient still on assisted breathing on transfer to another ICU naastbrend_transfer <input type="checkbox"/> Patient died by Study Day 90 naastbrend_death <input type="checkbox"/> Patient still on assisted breathing on Study Day 90 naastbrend_day90
Section: PICU Discharge		
6.	Date and time patient medically ready for off PICU service care	<input type="text"/> / <input type="text"/> / <input type="text"/> medready_dayssince day0 <input type="text"/> : <input type="text"/> 24-hour clock
7.	Date and time patient discharged from the PICU	<input type="text"/> / <input type="text"/> / <input type="text"/> picudis_dayssince day0 <input type="text"/> : <input type="text"/> 24-hour clock
8.	Location of PICU discharge	<input type="radio"/> Inpatient non-ICU area (1) <input type="radio"/> Step-down unit (your hospital) (2) picudisloc <input type="radio"/> Home (3) <input type="radio"/> Another ICU (your hospital) (4) <input type="radio"/> Another hospital's ICU closer to home (5) <input type="radio"/> Another hospital's ICU for subspecialty care (6) Patient deceased (8) <input type="radio"/> Chronic care or rehabilitation facility (7) Still in the PICU on Study Day 90 (9) <input type="radio"/> Other, (99) picudislocoth Note: Responses of (99) recategorized to (1) - (9) for ease of use specify:
9.	Comfort medications at PICU discharge	On narcotics: narcpicudis <input type="radio"/> Yes (1) <input type="radio"/> No (0) On benzodiazepines: benzpicudis <input type="radio"/> Yes (1) <input type="radio"/> No (0) On clonidine: clonpicudis <input type="radio"/> Yes (1) <input type="radio"/> No (0)

Section: Hospital Discharge

10.	Date patient discharged from your hospital	<input type="text" value=""/> / <input type="text" value=""/> / <input type="text" value=""/> hospdisc_dayssince0
11.	Location of hospital discharge	<input type="radio"/> Home (1) hospdiscloc <input type="radio"/> Another hospital (2) <input type="radio"/> Chronic care or rehabilitation facility (3) <input type="radio"/> Patient deceased (4) Still in the hospital on Study Day 90 (5) <input type="radio"/> Other: (99) hospdisclooth Responses of (99) recategorized to (1) - (5) for ease of use
12.	Did the parent/guardian provide consent for follow-up (see Form 2 question 19)?	<input type="radio"/> Yes (1) consentfu If Yes, did the subject assent/consent for the follow-up part of <i>RESTORE</i> ? assentfu <input type="radio"/> Yes (1) <input type="radio"/> N/A Subject < 8 years or subject's PCPC > 3 (2) <input type="radio"/> No Subject not off opioids for 72 hours at hospital discharge (3) <input type="radio"/> No Subject refused (0) <input type="radio"/> No, Other: (99) assentfuoth Note: assentfuoth has been recategorized for ease of use <input type="radio"/> No (0)
13.	Has the CRISMA Contact and Demographic Information form and the consent form been faxed to CRISMA?	<input type="radio"/> N/A (parent/guardian did not provide consent for follow-up) (2) <input type="radio"/> Yes (1) crismafm <input type="radio"/> No (0) Note: Removed to deidentify data
14.	Comfort medications at hospital discharge	On narcotics: narchospdis <input type="radio"/> Yes (1) <input type="radio"/> No (0) On benzodiazepines: benzhospdis <input type="radio"/> Yes (1) <input type="radio"/> No (0) On clonidine: clonhospdis <input type="radio"/> Yes (1) <input type="radio"/> No (0)
15.	PCPC score on day of hospital discharge	<input type="text" value=""/> Pulldown list 5 dispcpc
16.	POPC score on day of hospital discharge	<input type="text" value=""/> Pulldown list 6 dispopc

Section: Patient Death by Study Day 90

17.	Did the patient die?	<input type="radio"/> Yes, date of death: <input type="text" value=""/> / <input type="text" value=""/> / <input type="text" value=""/> death_dayssince0 (1) Primary cause of death: primdeath death
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		<p> <input type="radio"/> Respiratory failure(1) <input type="radio"/> Multisystem organ failure (2) <input type="radio"/> Sepsis/septic shock (3) <input type="radio"/> Trauma (4) <input type="radio"/> Cancer, (5) primcanc Note: Removed to deidentify data specify type: If cancer, did they have bone marrow transplant? <input type="radio"/> Yes(1) primdeathbmt Terminal neurological event (6) <input type="radio"/> No (0) <input type="radio"/> Other, (99) primdeathoth Note: Removed to deidentify data specify: </p> <p> <u>Secondary</u> cause of death: secdeath <input type="radio"/> Not Applicable (0) <input type="radio"/> Respiratory failure(1) <input type="radio"/> Multisystem organ failure (2) <input type="radio"/> Sepsis/septic shock (3) <input type="radio"/> Trauma (4) <input type="radio"/> Cancer, (5) seccanc Note: Removed to deidentify data specify type: If cancer, did they have bone marrow transplant? <input type="radio"/> Yes(1) secdeathbmt Terminal neurological event (6) <input type="radio"/> No (0) <input type="radio"/> Other, (99) secdeathoth Note: Removed to deidentify data specify: </p> <p> <input type="radio"/> No (0) </p>
18.	If patient died in your PICU, which of these circumstances applied?	<input type="radio"/> Failed resuscitation (1) <input type="radio"/> Associated with withdrawal/ limitation of care/ do not resuscitate order (DNR) (2) deathcirc <input type="radio"/> Brain death (3)

Form 9: Adverse Event

1.	Start date and time of event <input type="text"/> / <input type="text"/> / <input type="text"/> <input type="text"/> : <input type="text"/> 24-hour clock aest_dayssince0
2.	Is this event a "Specified <i>RESTORE</i> Event"; specifically is the event any of the following? <input type="radio"/> Yes (1) aespec "Specified <i>RESTORE</i> Event": <input type="radio"/> Inadequate pain management (1) <input type="radio"/> Inadequate sedation management (2) ae <input type="radio"/> Clinically significant iatrogenic withdrawal - Answer question 6 (3) <input type="radio"/> Unplanned ETT extubation - Answer question 7 (4) <input type="radio"/> Post extubation stridor with chest-wall retractions at rest - Answer question 8 (5) <input type="radio"/> Extubation failure - reintubation within 24 hours - Answer question 9 (6) <input type="radio"/> Unplanned removal of arterial access - Answer question 10 (7) <input type="radio"/> Unplanned removal of central venous access - Answer question 11 (8) <input type="radio"/> Unplanned removal of peripheral venous access - Answer question 12 (9) <input type="radio"/> Unplanned removal of nasogastric drainage tube - Answer question 13 (10) <input type="radio"/> Unplanned removal of bladder catheter - Answer question 14 (11) <input type="radio"/> Unplanned removal of chest tube - Answer question 15 (12) <input type="radio"/> Unplanned removal (13) aeothtube of "other" tube, specify and Answer question 16: <input type="radio"/> Ventilator-associated pneumonia (new this study day) - Answer question 17 (14) <input type="radio"/> Catheter-associated bloodstream infection (new this study day) - Answer question 18 (15) <input type="radio"/> Stage 2+ pressure ulcers (new this study day) - Answer question 19 (16) <input type="radio"/> Tracheostomy (new this study day) - Answer question 20 (17) <input type="radio"/> No(0) If No, describe the event: aeoth Note: aeoth was recategorized into COSTART categories Is the event expected in the clinical course of a critically ill pediatric patient supported on mechanical ventilation? <input type="radio"/> Yes (1) aeothexp <input type="radio"/> No (0)

		<p>All unexpected events must be reported to the site co-investigators within 24 hours.</p> <p>Is this AE related to sedation management? aesed</p> <p><input type="radio"/> Yes (1)</p> <p><input type="radio"/> No (0)</p>
3.	<p>What is the severity of this AE?</p>	<p><input type="radio"/> Mild: Did not require treatment; did not impact (in any way) the patient's course of illness (0)</p> <p><input type="radio"/> Moderate: Resolved with treatment; may have impacted the patient's course of illness but did not prolong existing hospitalization (1)</p> <p><input type="radio"/> Severe (2) aeseverity</p> <p>If Severe: aesevere</p> <p><input type="radio"/> Fatal (1)</p> <p><input type="radio"/> Immediately life-threatening (2)</p> <p><input type="radio"/> Severely incapacitating (3)</p> <p><input type="radio"/> Permanently disabling (4)</p> <p><input type="radio"/> Prolongs existing hospitalization (5)</p> <p><input type="radio"/> May require medical or surgical intervention to prevent one of the other outcomes listed in this definition (6)</p>
4.	<p>What is the relationship of this AE to the study?</p>	<p><input type="radio"/> Not related (0)</p> <p><input type="radio"/> Possible (1) aerel</p> <p><input type="radio"/> Probable (2)</p> <p><input type="radio"/> Definitely (3)</p>
5.	<p>If Unanticipated Problem or Reportable Serious Adverse Event, did the site co-investigator notify the local IRB?</p> <p>If an event was unanticipated, defined as:</p> <p>a) not a "specified event" or not related to the patient's underlying illness, and</p> <p>b) possibly, probably or definitely related to the <i>RESTORE</i> protocol, and</p> <p>c) involved actual or potential risk,</p> <p>OR</p> <p>If the event was a Reportable Serious Adverse Event, defined as:</p> <p>a) unexpected, and</p> <p>b) possibly, probably or definitely related, and</p>	<p><input type="radio"/> Yes (1) aeunexpsae</p> <p><input type="radio"/> No (0)</p> <p><input type="radio"/> Not applicable (2)</p> <p>End of form, unless a "Specified <i>RESTORE</i> Event" that requires follow-up questions was identified.</p>

<p>c) serious,</p> <p>the event must be reported by a site co-investigator to the IRB and to the <i>RESTORE</i> Principal Investigator, Dr. Martha Curley, at 215-573-9449 within 24 hours.</p>	
<p>6. Clinically significant iatrogenic withdrawal: Follow-up questions</p>	<p>WAT-1 score before rescue therapy: aeceiwatpre <input type="text" value="0-12"/></p> <p>WAT-1 score after "effective" rescue therapy: aeceiwatpost <input type="text" value="0-12"/></p>
<p>7. Unplanned ETT extubation: Follow-up questions</p>	<p>Last recorded SBS: aeelfextubsbs <input type="text" value="-3, -2, -1, 0, 1, 2"/></p> <p>Minutes from last sedative titration/administration of bolus: aeelfextubmin</p> <p>Oral or nasal ETT: aeelfextubett <input type="text" value="(1) Oral, (2) Nasal"/></p> <p>Nurse-patient ratio: aeelfextubratio <input type="text" value="(1) 1 nurse: 1 patient, (2) 1 nurse: 2 patients, (3) 1 nurse: 3 patients"/></p> <p>Occurred during nursing care: aeelfextubcare <input type="text" value="(1) Yes, (0) No"/></p> <p>Occurred with nurse at the bedside: aeelfextubnurse <input type="text" value="(1) Yes, (0) No"/></p> <p>Occurred with parent at the bedside: aeelfextubparent <input type="text" value="(1) Yes, (0) No"/></p> <p>Subject appears to be in an state of delirium: aeelfextubdel <input type="text" value="(1) Yes, (0) No"/></p>
<p>8. Post extubation stridor with chest-wall retractions at rest: Follow-up questions</p>	<p>ETT size: aestridorsize</p> <p>Oral or nasal ETT: aestridorett <input type="text" value="(1) Oral, (2) Nasal"/></p> <p>Cuffed ETT: aestridorcuff <input type="text" value="(1) Yes, (0) No"/></p> <p>Steroid use pre-extubation: aestridorster <input type="text" value="(1) Yes, (0) No"/></p> <p>Bronchoscopy for airway evaluation: aestridorbronch <input type="text" value="(1) Yes, (0) No"/></p>

		Diagnosis of post-extubation vocal cord paralysis: aestridorparal <input type="button" value="v"/> (1) Yes, (0) No History of difficult/traumatic intubation: aestridorhist <input type="button" value="v"/> (1) Yes, (0) No Current tracheal infection: aestridorinf <input type="button" value="v"/> (1) Yes, (0) No
9.	Extubation failure - reintubation within 24 hours: Follow-up question	Use of racemic epinephrine to prevent reintubation: aeextubfailepi <input type="button" value="v"/> (1) Yes, (0) No
10.	Unplanned removal of arterial access: Follow-up questions	SBS pre removal: aeartsbspre <input type="button" value="v"/> -3, -2, -1, 0, 1, 2 SBS post removal: aeartsbspost <input type="button" value="v"/> -3, -2, -1, 0, 1, 2
11.	Unplanned removal of central venous access: Follow-up questions	SBS pre removal: aecvlsbspre <input type="button" value="v"/> -3, -2, -1, 0, 1, 2 SBS post removal: aecvlsbspost <input type="button" value="v"/> -3, -2, -1, 0, 1, 2
12.	Unplanned removal of peripheral venous access: Follow-up questions	SBS pre removal: aepvlsbspre <input type="button" value="v"/> -3, -2, -1, 0, 1, 2 SBS post removal: aepvlsbspost <input type="button" value="v"/> -3, -2, -1, 0, 1, 2
13.	Unplanned removal of nasogastric drainage tube: Follow-up questions	SBS pre removal: aengtubesbspre <input type="button" value="v"/> -3, -2, -1, 0, 1, 2 SBS post removal: aengtubesbspost <input type="button" value="v"/> -3, -2, -1, 0, 1, 2
14.	Unplanned removal of bladder catheter: Follow-up questions	SBS pre removal: aeohtubesbspre <input type="button" value="v"/> -3, -2, -1, 0, 1, 2 SBS post removal: aeohtubesbspost <input type="button" value="v"/> -3, -2, -1, 0, 1, 2 Note: Questions 14-16 were combined as SBS pre removal: aeohtubesbspre SBS post removal: aeohtubesbspost
15.	Unplanned removal of chest tube: Follow-up questions	SBS pre removal: aeohtubesbspre <input type="button" value="v"/> -3, -2, -1, 0, 1, 2 SBS post removal: aeohtubesbspost <input type="button" value="v"/> -3, -2, -1, 0, 1, 2

<p>16. Unplanned removal of other tube: Follow-up questions</p>	<p>SBS pre removal: aeohtubesbspre <input type="button" value="v"/> -3, -2, -1, 0, 1, 2</p> <p>SBS post removal: aeohtubesbspost <input type="button" value="v"/> -3, -2, -1, 0, 1, 2</p>
<p>17. Ventilator-associated pneumonia: Follow-up questions</p>	<p>Is the subject noted to have a strong cough and gag reflex? aevapreflex <input type="button" value="v"/> (1) Yes, (0) No</p> <p>Did the subject receive CPR this episode of illness? aevapcpr <input type="button" value="v"/> (1) Yes, (0) No</p> <p>Did a chest x-ray report note any of the following: new or progressive and persistent infiltrate, consolidation, cavitation, pneumatoceles? aevapxray <input type="button" value="v"/> (1) Yes, (0) No</p> <p>Did the subject exhibit a temperature alteration (> 38 C or < 36.5 C)? aevaptemp <input type="button" value="v"/> (1) Yes, (0) No</p> <p>Did the subject exhibit Leukopenia (< 4,000 WBC/mm³) OR leukocytosis? aevapleuk</p> <ul style="list-style-type: none"> • For children ≤ 1 year old, leukocytosis is defined as ≥ 15,000 WBC/mm³ AND left shift (≥ 10% band forms) • For children > 1 year old and < 12 years old, leukocytosis is defined as ≥ 15,000 WBC/mm³ • For children ≥ 12 years old, leukocytosis is defined as ≥ 12,000 WBC/mm³ <p><input type="button" value="v"/> (1) Yes, (0) No</p> <p>Was a new onset purulent sputum, or change in character of sputum, or increased respiratory secretions, or increased suctioning requirements noted? aevapspatum <input type="button" value="v"/> (1) Yes, (0) No</p> <p>Was a new onset or worsening cough, or dyspnea, or tachypnea noted? aevapcough <input type="button" value="v"/> (1) Yes, (0) No</p> <p>Did the subject exhibit rales or bronchial breath sounds? aevaprales <input type="button" value="v"/> (1) Yes, (0) No</p> <p>Did the subject exhibit worsening gas exchange (e.g., oxygen desaturations (e.g., saturation < 94%, PaO₂/FIO₂ < 240), increased oxygen requirements, or increased ventilator demands)? aevapgas <input type="button" value="v"/> (1) Yes, (0) No</p> <p>Were positive culture results (urine, blood, sputum, BAL, protected brush, other) noted? aevappos <input type="button" value="v"/> (1) Yes, (0) No</p> <p>Were new antibiotics initiated? aevapabx <input type="button" value="v"/> (1) Yes, (0) No</p> <p>Was the VAP adjudicated by the local infectious disease officer (RN/MD)? aevapadj <input type="button" value="v"/> (1) Yes, (0) No</p>
<p>18. Catheter-associated bloodstream infection: Follow-up questions</p>	<p>Does the subject have a recognized pathogen cultured from one or more blood cultures? aecabsipath <input type="button" value="v"/> (1) Yes, (0) No</p>

		<p>Is the organism cultured from blood possibly related to an infection at another site? aecabsirel</p> <p><input type="button" value="v"/> (1) Yes, (0) No</p> <p>Does the subject have any of the following signs or symptoms of infection? aecabsiss</p> <ul style="list-style-type: none"> • For children ≤ 1 year of age: temperature alteration (> 38 C or < 36 C, core), chills, hypotension, apnea, bradycardia • For children > 1 year of age: temperature alteration (> 38 C or < 37 C), chills, hypotension <p><input type="button" value="v"/> (1) Yes, (0) No</p> <p>Could the above signs and symptoms be possibly related to an infection at another site? aecabsissrel</p> <p><input type="button" value="v"/> (1) Yes, (0) No</p> <p>Are common skin contaminants (see "CA-BSI Adjudication Process" document) cultured from two or more blood cultures drawn on separate occasions? aecabsicontam</p> <p><input type="button" value="v"/> (1) Yes, (0) No</p> <p>Are there any other positive culture results (urine, blood, sputum, BAL, protected brush, other)? aecabsipos</p> <p><input type="button" value="v"/> (1) Yes, (0) No</p> <p>Were new antibiotics initiated in response to this blood culture? aecabsiabx</p> <p><input type="button" value="v"/> (1) Yes, (0) No</p> <p>Did the subject have a central access device that terminated at or close to the heart or one of the great vessels in use during the 48-hour period before the development of the CA-BSI? aecabsicv</p> <p><input type="button" value="v"/> (1) Yes, (0) No</p> <p>Was the CA-BSI adjudicated by the local infectious disease officer (RN/MD)? aecabsiadj</p> <p><input type="button" value="v"/> (1) Yes, (0) No</p>
19.	Stage 2+ pressure ulcers: Follow-up questions	<p>Most recent Braden Q (see <i>RESTORE</i> study website): aelucerbradenq</p> <p><input type="button" value="v"/> 7-28</p> <p>Date of most recent Braden Q: aelucerbradenq_dayssince day0</p> <p><input type="button" value="v"/> / <input type="button" value="v"/> / <input type="button" value="v"/></p> <p>Location: aelucerloc</p> <p><input type="button" value="v"/> Pulldown list 7</p>
20.	Tracheostomy: Follow-up questions	<p>Rationale for new tracheostomy: aetrachrat</p> <p style="text-align: right; color: red;">Note: aetrachrat was recategorized for ease of use</p> <p>Tracheostomy secondary to agitation related airway trauma: aetrachsec</p> <p><input type="button" value="v"/> (1) Yes, (0) No</p>

RESTORE: Form 10: Protocol Deviations fm10

Form 10: Protocol Deviations

Note: All dates have been reformulated to be days since study day 0

1. Date of protocol deviation	<input type="text" value=""/> / <input type="text" value=""/> / <input type="text" value=""/>	pd_dayssince day0
2. Describe the protocol deviation:	pd	Note: pd has been recategorized for ease of use
3. Was the local IRB notified?	<input type="radio"/> Yes, date notified: <input type="text" value=""/> / <input type="text" value=""/> / <input type="text" value=""/> (1) pdirb <input type="radio"/> No (0) pdirb_dayssince day0	Note: pdirb and pdirb_dayssince day0 have been removed; used for internal quality monitoring

Pulldown list 1 **Note: (4) and (5) have been collapsed to (4)**

- (1) Normal
- (2) Mild disability
- (3) Moderate disability
- (4) Severe disability
- (5) Coma or vegetative state

Pulldown list 2 **Note: (4) and (5) have been collapsed to (4)**

- (1) Good overall performance
- (2) Mild overall disability
- (3) Moderate overall disability
- (4) Severe overall disability
- (5) Coma or vegetative state

Pulldown list 3

- (32) Acetaminophen (Tylenol) mg
- (34) Tylenol with codeine mg
- (1) Chloral Hydrate (Aquachloral) mg
- (2) Clonazepam (Klonopin) mg
- (3) Clonidine (Catapres) mcg
- (4) Codeine mg
- (5) Dexmedetomidine (Precedex) mcg
- (6) Diazepam (Valium) mg
- (7) Diphenhydramine (Benadryl) mg
- (8) Droperidol (Inapsine) mg
- (9) Etomidate (Amidate) mg
- (10) Flumazenil (Romazicon) mg
- (11) Haloperidol (Haldol) mg
- (12) Hydromorphone (Dilaudid) mg
- (13) Hydroxyzine (Atarx, Vistaril) mg
- (33) Ibuprofen (Advil, Motrin) mg
- (14) Ketamine (Ketalar) mg
- (15) Ketorolac (Toradol) mg
- (16) Melatonin mg
- (17) Meperidine (Demerol) mg
- (18) Nalbuphine Hydrochloride (Nubain) mg
- (19) Naloxone Hydrochloride (Narcan) mg
- (20) Olanzapine (Zyprexa) mg
- (21) Oxycodone immediate release (Oxycontin) mg
- (22) Oxycodone sustained release (Oxycontin) mg
- (23) Pentobarbital (Nembutal) mg
- (24) Pentothal sodium (Thiopental) mg
- (25) Phenobarbital (Luminal) mg
- (26) Propofol (Diprivan) mcg

- (27) Risperidone (Risperdal) mg
- (28) Sufentanil (Sufenta) mcg
- (29) Sweet-Ease (oral sucrose) *(dose not required)
- (30) Zolpidem (Ambien) mg
- (31) Any inhalation anesthetic *(dose not required)
- (99) Other
- (35) Remifentanil **Note: Category added post-hoc**

Pulldown list 4

- (1) Patient transferred out of the PICU after receiving < 5 days of narcotics **(Forms 4a, 4b only)**
- (9) Patient transferred back to PICU for management of a new clinical problem not related to the use/weaning of sedation **(Forms 5a, 5b only)**
- (2) Patient did not receive narcotics in the PICU in the past 72 hours
- (3) Patient discharged from hospital
- (4) Study Day 28
- (5) Patient transferred in-house to a non-participating ICU
- (6) Withdrawal of consent **(Forms 4a, 5a only)**
- (8) Patient withdrawn from study **(Forms 4b, 5b only)**
- (7) Redirection of care

Pulldown list 5

- (1) Normal
- (2) Mild disability
- (3) Moderate disability
- (4) Severe disability
- (5) Coma or vegetative state
- (6) Brain death

Pulldown list 6

- (1) Good overall performance
- (2) Mild overall disability
- (3) Moderate overall disability
- (4) Severe overall disability
- (5) Coma or vegetative state
- (6) Brain death

Pulldown list 7

- (1) Occiput
- (2) Ear
- (3) Chin
- (4) Neck
- (5) Clavicle
- (6) Sternum
- (7) Chest

- (8) Shoulder
- (9) Elbow
- (10) Wrist
- (11) Scapula
- (12) Vertebrae
- (12) Sacrum
- (13) Coccyx
- (15) Ischial tuberosity
- (16) Trochanter
- (17) Iliac crest
- (18) Knee
- (19) Lower leg
- (20) Ankles
- (21) Heels
- (22) Toes