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FILL OUT FOR ALL PATIENTS WITH ARDS >= 7 DAYS AND <= 28 DAYS WHO MEET SCREENING CRITERIA IN DESIGNATED ICUs	
<p>1. Has patient had all of the following within a 24 hour interval?</p> <ul style="list-style-type: none"> PaO₂/FiO₂ <= 200 mm Hg (if altitude > 1000m use (PaO₂/FiO₂) x (Pbar/760)) <ul style="list-style-type: none"> Bilateral infiltrates Receiving positive pressure ventilation via endotracheal tube <ul style="list-style-type: none"> No clinical evidence of left atrial hypertension (if measured pulmonary arterial wedge pressure <= 18 mm Hg) 	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
<p>2. Date these criteria exist simultaneously (date of ARDS onset):</p>	<input type="text"/> <input type="button" value="Date"/>
<p>3. Has patient had ARDS for greater than or equal to 7 and less than or equal to 28 days since onset?</p>	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
<p>4. Gender:</p>	<input type="radio"/> No Answer <input type="radio"/> Male (1) <input type="radio"/> Female (2)
<p>NOTE: this item has been modified to deidentify the data. All responses of 3,4,5, or 6 were grouped to show a response of 6.</p> <p>5. Ethnicity:</p>	<input type="radio"/> No Answer <input type="radio"/> White, not of Hispanic Origin (1) <input type="radio"/> Black, not of Hispanic Origin (2) <input type="radio"/> Hispanic (3) <input type="radio"/> Asian/Pacific Islander (4) <input type="radio"/> American Indian/Alaskan Native (5) <input type="radio"/> Other (6)
<p>NOTE: ages greater than 89 are reported as 89 to deidentify data</p> <p>6. Age:</p>	<input type="text"/>
<p>7. Hospital location:</p>	<input type="radio"/> No Answer <input type="radio"/> MICU (1) <input type="radio"/> SICU (2) <input type="radio"/> Cardiac SICU (3) <input type="radio"/> CCU (4) <input type="radio"/> Neuro ICU (5) <input type="radio"/> Burn (6) <input type="radio"/> Trauma (7) <input type="radio"/> Cancer Unit (8) <input type="radio"/> MICU/SICU (9) <input type="radio"/> Other (10)
<p>8. Lung Injury Category</p>	
<p>8a. Trauma:</p>	<input type="radio"/> No Answer <input type="radio"/> Secondary (2) <input type="radio"/> Primary (1)

screen1

adate

onset

gender

ethnic

age

loc

trauma

table= screen

	(1) <input type="radio"/> None (0)	
8b. Sepsis:	<input type="radio"/> No Answer <input type="radio"/> Secondary (2) <input type="radio"/> Primary (1) <input type="radio"/> None (0)	sepsis
8c. Multiple transfusions:	<input type="radio"/> No Answer <input type="radio"/> Secondary (2) <input type="radio"/> Primary (1) <input type="radio"/> None (0)	multran
8d. Aspiration:	<input type="radio"/> No Answer <input type="radio"/> Secondary (2) <input type="radio"/> Primary (1) <input type="radio"/> None (0)	aspir
8e. Pneumonia:	<input type="radio"/> No Answer <input type="radio"/> Secondary (2) <input type="radio"/> Primary (1) <input type="radio"/> None (0)	pneum
8f. Other: (specify below)	<input type="radio"/> No Answer <input type="radio"/> Secondary (2) <input type="radio"/> Primary (1) <input type="radio"/> None (0)	othr
8g. Other:	<input type="text"/>	other
<p>NOTE: some "other" entries have been modified to deidentify data</p> 9. Primary Reason for Exclusion or Nonenrollment:	<input type="radio"/> No Answer <input type="radio"/> Not Excluded (0) <input type="radio"/> MD Refusal (1) <input type="radio"/> Patient/Family Refusal (2) <input type="radio"/> Patient Unable/Surrogate Unavailable (3) <input type="radio"/> Patient Under 13 Years of Age (4) <input type="radio"/> Other Trial 30 Days (5) <input type="radio"/> Patient is Pregnant (6) <input type="radio"/> Burns Requiring Graft (7) <input type="radio"/> AIDS or Prednisone >15 mg/d or Cytotoxic Rx 3 Weeks (8) <input type="radio"/> Terminal Illness (9) <input type="radio"/> Not Committed to Full Support (10) <input type="radio"/> Chronic Liver Disease (11) <input type="radio"/> Bone/Lung Transplant (12) <input type="radio"/> Chronic Respiratory Disease (13) <input type="radio"/> New Pneumonia (14) <input type="radio"/> Abscess (15) <input type="radio"/> Fungal Infection (16) <input type="radio"/> Disqualifying Criteria Met (17) <input type="radio"/> Adrenal Insufficiency (18) <input type="radio"/> Vasculitis (19) <input type="radio"/> Ongoing Septic Shock (20) <input type="radio"/> Extubated > 24 hours (21) <input type="radio"/> Never Met Severity Criteria (22) <input type="radio"/> Died Before 28 Days (23)	prime
10. Date qualifying criteria obtained:	<input type="text"/> <input type="button" value="Date"/>	adate1
ENTER QUALIFYING CRITERIA (FOR THOSE ENROLLED) OBTAINED DURING		

table= screen

REFERENCE PERIOD 0600-1000. IF MORE THAN ONE VALUE, ENTER BEST. IF NOT AVAILABLE DURING REFERENCE PERIOD, USE BEST VALUE CLOSEST TO 0800.	
11. PaO2:	<input type="text"/> mm Hg
13. FiO2:	<input type="text"/>
15. PEEP:	<input type="text"/> cm H2O

screen2

screen3

screen5

Enrollment Criteria [table= enrollme](#)

Visit Date: [visit](#)

<p>1. Is the attending physician unwilling to participate?</p>	<p> <input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) </p> <p style="text-align: right;">atmd</p>
<p>2. Does the patient or family refuse study participation?</p>	<p> <input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) </p> <p style="text-align: right;">ptre</p>
<p>3. Unable to Obtain Informed Consent?</p>	<p> <input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) </p> <p style="text-align: right;">noic</p>
<p>4. Is the patient under 13 years of age?</p>	<p> <input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) </p> <p style="text-align: right;">ls13</p>
<p>5. Has the patient participated in other trials within the last 30 days?</p>	<p> <input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) </p> <p style="text-align: right;">otrls</p>
<p>6. Is the patient pregnant? (if yes, HCG is required):</p>	<p> <input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) </p> <p style="text-align: right;">ptpg</p>
<p>7. Does the patient have burns requiring skin grafting?</p>	<p> <input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) </p> <p style="text-align: right;">brns</p>
<p>8. Does the patient have AIDS or has s/he received prednisone therapy or cytotoxic therapy?</p>	<p> <input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) </p> <p style="text-align: right;">aids</p>
<p>9. Does the patient have a malignancy or other chronic irreversible disease with 6 mo mortality estimated at greater than 50%?</p>	<p> <input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) </p> <p style="text-align: right;">mort</p>
<p>10. Is physician</p>	

table= enrollme

not committed to full support?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	nofs
11. Does the patient have severe, chronic liver disease? (If Child-Pugh score is greater than or equal to 10, enter yes):	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	sclد
CHILD-PUGH SCORE: (11a-11e) NOTE: FOR 11B USE FOLLOWING: <ul style="list-style-type: none"> • No abnormality • Grade I or II: Trivial lack of awareness; shortened attention span; lethargy; disorientation in time; clear personality changes, or inappropriate behavior • Grade III or IV: Very drowsy; semicomatose but responsive to stimuli; confused; gross disorientation in time or space; bizarre behavior; coma; unresponsive to painful stimuli w/ or w/o abnormal movements 		
11a. Does the patient have ascites?	<input type="radio"/> No Answer <input type="radio"/> Tense (3) <input type="radio"/> Present (2) <input type="radio"/> None (1)	asci
11b. Does the patient have encephalopathy?	<input type="radio"/> No Answer <input type="radio"/> Grade III or IV (3) <input type="radio"/> Grade I or II (2) <input type="radio"/> None (1)	ence
11c. Bilirubin (mg/dl):	<input type="radio"/> No Answer <input type="radio"/> [>3] (3) <input type="radio"/> [2-3] (2) <input type="radio"/> [<2] (1)	bili
11d. Albumin (g/dl):	<input type="radio"/> No Answer <input type="radio"/> [<2.8] (3) <input type="radio"/> [2.8-3.5] (2) <input type="radio"/> [>3.5] (1)	alb
11e. Prothrombin Time (sec. prolonged):	<input type="radio"/> No Answer <input type="radio"/> [>10] (3) <input type="radio"/> [5-10] (2) <input type="radio"/> [1-4] (1)	prot
11f. Total Child-Pugh Score:	<input type="text"/>	pugh
12. Has the patient had a transplant?		

table= enrollme

<p>(excepting autologous bone marrow transplants not meeting the criteria of question 9):</p>	<p><input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)</p> <p style="text-align: right;">trnp</p>
<p>13. Does the patient have severe chronic respiratory disease or other chronic disease (s) of the lung, chest wall, or neuromuscular system?</p>	<p><input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)</p> <p style="text-align: right;">scopd</p>
<p>14. Does the patient have a new diagnosis of pneumonia with less than 72 hours appropriate therapy at the time of screening?</p>	<p><input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)</p> <p style="text-align: right;">ndxp</p>
<p>15. Does patient have a known, undrained abscess?</p>	<p><input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)</p> <p style="text-align: right;">unab</p>
<p>16. Does patient have a disseminated fungal infection?</p>	<p><input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)</p> <p style="text-align: right;">fung</p>
<p>17. Does patient have known or suspected adrenal insufficiency?</p>	<p><input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)</p> <p style="text-align: right;">adrenal</p>
<p>18. Does patient have vasculitis or diffuse adrenal hemorrhage?</p>	<p><input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)</p> <p style="text-align: right;">adhem</p>
<p>19. Does patient suffer from ongoing septic shock?</p>	<p><input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)</p> <p style="text-align: right;">seps shock</p>
<p>20a. Has informed consent been</p>	<p><input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)</p> <p style="text-align: right;">consent</p>

table= enrollme

obtained for participation in LaSRS?	
20b. Has informed consent been obtained for genetic testing in LaSRS?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) gene1
20c. Has informed consent been obtained for genetic testing in all ARDSNet studies?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) gene2
"If patient is eligible and consent for the study has been obtained, please call for randomization number"	
21. Is patient randomized?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) ptrb
22a. Date of randomization:	<input type="text"/> <input type="button" value="Date"/> randdt
22b. Time of patient randomization:	<input type="text"/> NOTE: "rtime" has been removed to protect patient identity rtime
23. Patient Randomization Number:	<input type="text"/> subject

NOTE: "subject" has been recoded in all tables and renamed "ptid"

Adverse Event table= ae

Visit Date: visit

1. Date of adverse event:	<input type="text"/> <input type="button" value="Date"/>	aevent1
2a. Specify adverse event:	<input type="radio"/> No Answer <input type="radio"/> Uncontrolled hyperglycemia (1) <input type="radio"/> Wound dehiscence (2) <input type="radio"/> Acute psychosis (3) <input type="radio"/> Acute pancreatitis (4) <input type="radio"/> Other adverse event [specify below] (5) <input type="radio"/> Death (6)	aevent2
2b. Other adverse event -- specify:	NOTE: some entries modified to deidentify data	aevent3
3. Describe event or problem:	NOTE: field dropped to deidentify data	aevent4
4. Severity of adverse event:	<input type="radio"/> No Answer <input type="radio"/> Mild (1) <input type="radio"/> Moderate (2) <input type="radio"/> Severe (3)	aevent5
5. Did AE require therapeutic intervention to avoid permanent impairment?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	aevent6
6. Was the patient in immediate risk of death due to adverse event?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	aevent7
7. Did patient die as a result of adverse event?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	aevent8
8. Was the event unexpected in ARDS or more severe/frequent than expected in ARDS?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) <input type="radio"/> Unknown (3)	aevent9
9. Causal relationship to study drug?	<input type="radio"/> No Answer <input type="radio"/> Definitely associated (1) <input type="radio"/> Probably associated (2) <input type="radio"/> Possible association (3) <input type="radio"/> Probably not associated (4) <input type="radio"/> Definitely not associated (5) <input type="radio"/> Uncertain association (6)	aevent10
10. Was study drug discontinued as a result of this event?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	aevent11
11a. Outcome to date:	<input type="radio"/> No Answer <input type="radio"/> Recovered -- give date of recovery below: (1) <input type="radio"/> AE present, no treatment (2) <input type="radio"/> AE present, being treated (3) <input type="radio"/> Residual effect, no treatment (4) <input type="radio"/> Residual effect, being treated (5) <input type="radio"/> Deceased (6)	aevent12

table= ae

11b. Date of recovery:	<input type="text"/> <input type="button" value="Date"/>	aevent13
12a. Final outcome of this adverse event:	<ul style="list-style-type: none"><input type="radio"/> No Answer<input type="radio"/> Recovered -- give date of recovery below: (1)<input type="radio"/> AE present, no treatment (2)<input type="radio"/> AE present, being treated (3)<input type="radio"/> Residual effect, no treatment (4)<input type="radio"/> Residual effect, being treated (5)<input type="radio"/> Deceased as a result of adverse effect (6)	aevent14
12b. Date of recovery:	<input type="text"/> <input type="button" value="Date"/>	aevent15

APACHE III ABG table= apache_a

Visit Date: visit

USE VALUES FROM 24 HRS PRECEDING RANDOMIZATION				
FiO2	PaO2 (mm Hg)	PaCO2 (mm Hg)	pH	Intubated when ABG obtained?
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)

fio2

pao2

paco2

ph

intubat

APACHE III Demographics table= apache_d

Visit Date: visit

1a. Hospital Admission Date:	<input type="text"/> <input type="button" value="Date"/>	hadmdt
1b. Hospital Admission Type:	<input type="radio"/> No Answer <input type="radio"/> Medical (1) <input type="radio"/> Surgical, scheduled (2) <input type="radio"/> Surgical, unscheduled (3) <input type="radio"/> Other (4)	admtype
2. ICU Admission Date:	<input type="text"/> <input type="button" value="Date"/>	icudt
3. Time of admission to ICU:	<input type="text"/> NOTE: "icutm" has been	icutm
4. Patient Admitted Directly From:	<input type="radio"/> No Answer <input type="radio"/> OR (1) <input type="radio"/> Recovery Room (2) <input type="radio"/> ER (3) <input type="radio"/> Floor (4) <input type="radio"/> Another Special Care Unit (5) <input type="radio"/> Another Hospital (6) <input type="radio"/> Direct Admit (7) <input type="radio"/> Stepdown Unit (8)	removed to protect patient identity admfrm
5. Is patient immediately post-operative from elective surgery?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	surgel
6. Was patient readmitted to ICU?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	icure
7. Was patient readmitted to ICU within 24 hours?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	icure2
8a. Is chronic health information available?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	chrnc
8b. Is patient on chronic dialysis or peritoneal dialysis?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	dialy
9a. Does patient have AIDS? (do not include HIV positive status without AIDS criteria):	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	aids2
9b. Does patient have leukemia? (AML, CML, all lymphocytic leukemias, multiple myeloma):	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	leuk
9c. Does patient have Non-Hodgkin's Lymphoma?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	lymph
9d. Does patient have a solid tumor with metastasis?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	tumor
9e. Is patient immunosuppressed? (radiation, chemotherapy, or		

table= apache_d

greater than/equal to 0.3 mg/kg/day prednisone or equivalent in past 6 mo):	<input type="radio"/> No Answer	<input type="radio"/> Yes (1)	<input type="radio"/> No (2)	immune
9f. Does patient have hepatic failure with coma or encephalopathy?	<input type="radio"/> No Answer	<input type="radio"/> Yes (1)	<input type="radio"/> No (2)	hepa
9g. Does patient have cirrhosis?	<input type="radio"/> No Answer	<input type="radio"/> Yes (1)	<input type="radio"/> No (2)	cirr
9h. Does patient have diabetes mellitus?	<input type="radio"/> No Answer	<input type="radio"/> Yes (1)	<input type="radio"/> No (2)	diab
9i. Protocol defined alcohol use?	<input type="radio"/> No Answer	<input type="radio"/> Yes (1)	<input type="radio"/> No (2)	ethanol

USE VALUES FROM 24 HRS PRECEDING RANDOMIZATION		
VITAL SIGNS	Lowest	Highest
1. Temperature:	<input type="text" value="tempcl"/> C <input type="text" value="tempfl"/> F	<input type="text" value="tempch"/> C <input type="text" value="tempfh"/> F
2. Systolic blood pressure:	<input type="text" value="sysbpl"/> mm Hg	<input type="text" value="sysbph"/> mm Hg
3. Mean arterial pressure:	<input type="text" value="meanapl"/> mm Hg	<input type="text" value="meanaph"/> mm Hg
4. Heart rate:	<input type="text" value="hratel"/> beats/min	<input type="text" value="hrateh"/> beats/min
5. Respiratory rate:	<input type="text" value="respl"/> breaths/min	<input type="text" value="resph"/> breaths/min
6a. Was patient ventilated when the lowest respiratory rate occurred?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) <input type="text" value="lvent"/>	
6b. Was patient ventilated when the highest respiratory rate occurred?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) <input type="text" value="hvent"/>	
7. Urine output in last 24 hours:	<input type="text" value="urine"/> ml	
HEMATOLOGY	Lowest	Highest
8. Hematocrit:	<input type="text" value="hctl"/> %	<input type="text" value="hcth"/> %
9. White blood cell count:	<input type="text" value="wbcl"/> cells/mm ³	<input type="text" value="wbch"/> cells/mm ³
10. Lowest platelet count:	<input type="text" value="plate"/> x 1000 cells/mm ³	
CHEMISTRY	Lowest	Highest
11. Sodium:	<input type="text" value="sodiuml"/> mEq/L	<input type="text" value="sodiumh"/> mEq/L
12. Potassium:	<input type="text" value="potasl"/> mEq/L	<input type="text" value="potash"/> mEq/L
13. Highest BUN:		<input type="text" value="bun"/> mg/dL
14. Creatinine:	<input type="text" value="creatl"/> mg/dL	<input type="text" value="creath"/> mg/dL
15. Glucose:	<input type="text" value="glucl"/> mg/dL	<input type="text" value="gluch"/> mg/dL
16. Albumin level:	<input type="text" value="albuml"/> g/dL	<input type="text" value="albumh"/> g/dL
17. Highest serum bilirubin:		<input type="text" value="sbili"/> mg/dL
18. Lowest serum bicarbonate:	<input type="text" value="bicar"/> mEq/L	

table= apache_p

19. Amylase:	<input type="text" value="amyl"/> units/L	<input type="text" value="amylh"/> units/L
20. Chloride:	<input type="text" value="chlorl"/> mEq/L	<input type="text" value="chlorh"/> mEq/L

Chest X-Ray [table= chest_xr](#)

Visit Date: [visit](#)

USE MOST RECENT CXR PRIOR TO TIME OF ENROLLMENT.	
1. Radiographic Lung Injury Score (# of quadrants):	<input type="text"/>
2. Barotrauma:	
2a. Pneumothoraces:	<input type="radio"/> No Answer <input type="radio"/> Right (1) <input type="radio"/> Left (2) <input type="radio"/> Bilateral (3) <input type="radio"/> None (4)
2b. Subcutaneous emphysema:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
2c. Pneumomediastinum:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
2d. Pneumatocoles > 2 cm diameter:	<input type="radio"/> No Answer <input type="radio"/> Right (1) <input type="radio"/> Left (2) <input type="radio"/> Bilateral (3) <input type="radio"/> None (4)
3. Chest tube:	<input type="radio"/> No Answer <input type="radio"/> Right (1) <input type="radio"/> Left (2) <input type="radio"/> Bilateral (3) <input type="radio"/> None (4)

[radlis](#)

[baro1](#)

[baro2](#)

[baro3](#)

[baro4](#)

[ctube](#)

Baseline Glasgow Coma Assessment table= glasgow Visit Date: visit

1. Is patient on a sedative or neuromuscular blocker? (If yes, use best GCS estimate)	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	sedate
2. Eye opening score:	<input type="radio"/> No Answer <input type="radio"/> Spontaneous (4) <input type="radio"/> To Voice (3) <input type="radio"/> To Pain (2) <input type="radio"/> None (1)	eye
3. Motor response score:	<input type="radio"/> No Answer <input type="radio"/> Obeys commands (6) <input type="radio"/> Localizes to Pain (5) <input type="radio"/> Flexor withdrawal (4) <input type="radio"/> Abnormal flexion (3) <input type="radio"/> Extension (2) <input type="radio"/> Flaccid (1)	motor
4. Verbal response score:	<input type="radio"/> No Answer <input type="radio"/> Oriented [or appears oriented, if on ventilator] (5) <input type="radio"/> Confused [or questionably oriented, if on ventilator] (4) <input type="radio"/> Inappropriate [or generally unresponsive, if on ventilator] (3) <input type="radio"/> Incomprehensible (2) <input type="radio"/> None (1)	verbal
5. Total GCS:	<input type="text"/>	gcst
IF PATIENT ON NEUROMUSCULAR BLOCKERS LAST 24 HOURS --> FORM COMPLETE.		
6. Does patient follow commands?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	cmds
7. Neck flexor?	<input type="radio"/> No Answer <input type="radio"/> No contraction (1) <input type="radio"/> Trace contraction (2) <input type="radio"/> Active contraction against gravity (3) <input type="radio"/> Active movement against gravity and resistance (4) <input type="radio"/> Normal power (5)	nckflex
8. Neck extensor?	<input type="radio"/> No Answer <input type="radio"/> No contraction (1) <input type="radio"/> Trace contraction (2) <input type="radio"/> Active contraction against gravity (3) <input type="radio"/> Active movement against gravity and resistance (4) <input type="radio"/> Normal power (5)	nckext

table= glasgow

9a. Leg flexor (leg lifting), right leg:	<input type="radio"/> No Answer <input type="radio"/> No contraction (1) <input type="radio"/> Trace contraction (2) <input type="radio"/> Active contraction against gravity (3) <input type="radio"/> Active movement against gravity and resistance (4) <input type="radio"/> Normal power (5)	lgflexrt
9b. Leg flexor (leg lifting), left leg:	<input type="radio"/> No Answer <input type="radio"/> No contraction (1) <input type="radio"/> Trace contraction (2) <input type="radio"/> Active contraction against gravity (3) <input type="radio"/> Active movement against gravity and resistance (4) <input type="radio"/> Normal power (5)	lgflexlt
10. Biceps deep tendon reflex:	<input type="radio"/> No Answer <input type="radio"/> Absent (0) <input type="radio"/> Diminished (1) <input type="radio"/> Normal (2) <input type="radio"/> Hyperactive (3) <input type="radio"/> Hyperactive with clonus (4)	bcpref
11. Achilles deep tendon reflex:	<input type="radio"/> No Answer <input type="radio"/> Absent (0) <input type="radio"/> Diminished (1) <input type="radio"/> Normal (2) <input type="radio"/> Hyperactive (3) <input type="radio"/> Hyperactive with clonus (4)	achref
12a. Has spontaneous upper extremity movement been observed in last 24 hours?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	athetupp
12b. Has spontaneous lower extremity movement been observed in last 24 hours?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	athetlow
13. Are fasciculations or fibrillations present?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	fasic

NOTE: Baseline and On-Study Glasgow Coma data are all found in the same table. The On-Study version of this CRF is found on page 27.

Baseline Medication Report [table= medicati](#)

Visit Date: [visit](#)

INDICATE 1=YES, 2=NO IF ANY OF THE FOLLOWING MEDICATIONS WERE ADMINISTERED DURING THIS CALENDAR DAY		
1. Sedatives/tranquilizers? (benzodiazepines, narcotics, barbiturates, propofol):	<input checked="" type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	seds
2. Neuromuscular blocking agents?	<input checked="" type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	nmba
3. Antifungal Imidazole? (eg. Fluconazole):	<input checked="" type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	antif
4. Amphotericin?	<input checked="" type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	ampho
5. Aminoglycosides?	<input checked="" type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	amino
5a. If yes, select antibiotics in this category (all that apply):	<input type="checkbox"/> Gentamicin (1) <input type="checkbox"/> Tobramycin (2) <input type="checkbox"/> Amikacin (3) <input type="checkbox"/> Other aminoglycosides (4)	amino12 amino13 amino14 amino15
6. Cephalosporins?	<input checked="" type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	ceph
6a. If yes, select antibiotics in this category (all that apply):	<input type="checkbox"/> Cefazolin (1) <input type="checkbox"/> Cefotaxime (2) <input type="checkbox"/> Cefotetan (3) <input type="checkbox"/> Ceftazidime (4) <input type="checkbox"/> Ceftriaxone (5) <input type="checkbox"/> Cefuroxime (6) <input type="checkbox"/> Cefepime (7) <input type="checkbox"/> Other cephalosporins (8)	ceph12 ceph13 ceph14 ceph15 ceph16 ceph17 ceph18 ceph19
7. Macrolides?	<input checked="" type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	mac
7a. If yes, select antibiotics in this category (all that apply):	<input type="checkbox"/> Azithromycin (1) <input type="checkbox"/> Clarithromycin (2) <input type="checkbox"/> Clindamycin (3) <input type="checkbox"/> Erythromycin (4)	mac12 mac13 mac14 mac15
8. Penicillins?	<input checked="" type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	pcn
8a. If yes, select antibiotics in this category (all that apply):	<input type="checkbox"/> Ampicillin (1) <input type="checkbox"/> Ampicillin-Subactam (2) <input type="checkbox"/> Aztreonam (3) <input type="checkbox"/> Imipenam-Cilistatin (4) <input type="checkbox"/> Nafcillin (5) <input type="checkbox"/> Penicillin (6) <input type="checkbox"/> Piperacillin (7) <input type="checkbox"/> Ticarcillin (8)	pcn12 pcn13 pcn14 pcn15 pcn16 pcn17 pcn18 pcn19

table= medicati

	<input type="checkbox"/> Other penicillins (9)	pcn20
9. Quinolones?	<input checked="" type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	quino
9a. If yes, select antibiotics in this category (all that apply):	<input type="checkbox"/> Ciprofloxacin (1) <input type="checkbox"/> Ofloxacin (2) <input type="checkbox"/> Other quinolones (3)	quino12 quino13 quino14
10. Vancomycin administered?	<input checked="" type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	vanco
11. Other antibiotics administered?	<input checked="" type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	oant
12. Antipsychotics administered?	<input checked="" type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	apsych
13. Nitric oxide administered?	<input checked="" type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	nox
14. Prone positioning?	<input checked="" type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	prone
15. Antivirals administered?	<input checked="" type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	avrls
Day 0 Study Drug Dosing		
16. Did patient receive study drug between time of randomization and midnight?	<input checked="" type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	dose1
16a. If yes, enter total dose administered:	<input type="text"/> mg	dose2

**NOTE: Baseline and On-Study Medications data are all found in the same table.
The On-Study version of this CRF is found on page 29.**

Baseline Ventilator Parameters [table= vent](#)

Visit Date: [visit](#)

ENTER VALUES FROM THE 4-HOUR INTERVAL PRIOR TO THE TIME OF RANDOMIZATION. IF MORE THAN ONE, USE MOST RECENT VALUES.	
1. Ventilator mode (all that apply):	
1a. SIMV?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
1b. Pressure support?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
1c. Assist/Control?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
1d. Pressure control?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
1e. PC IRV?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
1f. Other:	<input type="text"/>
2. Calculated delivered tidal volume:	<input type="text"/> ml
3. Pressure control level (if on pressure control ventilation):	<input type="text"/> cm H2O
4. Pressure support level (if on pressure support ventilation):	<input type="text"/> cm H2O
5. Set rate:	<input type="text"/> breaths/min
6. Total respiratory rate:	<input type="text"/> breaths/min
7. Total minute ventilation:	<input type="text"/> L/min
8. PEEP:	<input type="text"/> cm H2O
9. Plateau pressure (cm H2O, 0.5 sec end-inspiratory pause):	<input type="text"/> cm H2O
10. FiO2:	<input type="text"/>
11. PaO2:	<input type="text"/> mm Hg
12. PaCO2:	<input type="text"/> mm Hg
13. Arterial pH:	<input type="text"/>
14. SpO2:	<input type="text"/> %
15. Static Thoracic Compliance:	<input type="text"/> mL/cm H2O/kg IBW
16. Patient position:	<input type="radio"/> No Answer <input type="radio"/> Supine (1) <input type="radio"/> Prone (2) <input type="radio"/> Other (3)

ventm1
ventm2
ventm3
ventm4
ventm5
ventm6
cdtv
pcl
psvp
srat
trespr
tmnvnt
peep
platp
fio2vent
pao2vent
paco2_vt
artph
sats
stc
pposit

NOTE: Baseline and On-Study Vent Parameters data are all found in the same table. The On-Study version of this CRF is found on page 31.

Baseline Vital Signs [table= vitals](#)

Visit Date: [visit](#)

USE MOST RECENT VALUES IN THE 24 HOUR PERIOD PRIOR TO THE TIME OF RANDOMIZATION	
1. Heart rate:	<input type="text"/> beats/min hrate
2. Systolic blood pressure:	<input type="text"/> mm Hg sysbp
3. Diastolic blood pressure:	<input type="text"/> mm Hg diasbp
NOTE: height and weight outliers have been removed to deidentify data. 4. Temperature:	<input type="text"/> C <input type="text"/> F ctemp ftemp
5. Height:	<input type="text"/> cm <input type="text"/> in cheight iheight
6. Gender:	<input type="radio"/> No Answer <input type="radio"/> Male (1) <input type="radio"/> Female (2) gender
7. Calculated Predicted Body Weight:	<input type="text"/> kg pbw
8. Measured body weight:	<input type="text"/> kg <input type="text"/> lbs kweight lweight
9. Hematocrit:	<input type="text"/> % crit
10. White blood cell count:	<input type="text"/> cells/mm ³ wbcct
11. Glucose:	<input type="text"/> mg/dL glucose
12. Amylase:	<input type="text"/> units/L amylase
13. Albumin level:	<input type="text"/> g/dL albumin
14a. Prothrombin time:	<input type="text"/> sec prothr
14b. PT Control:	<input type="text"/> sec ptcont
IF TEMPERATURE > 38.5 C OR WBC > 15,000, SUGGEST CXR (IF NOT ALREADY DONE) AND OBTAIN TRACHEAL ASPIRATE FOR GRAM STAIN AND CULTURE. EXAMINE FOR LINE INFECTION, ABDOMINAL INFECTION, AND SINUSITIS.	

NOTE: Baseline and On-Study Vital Signs data are all found in the same table. The On-Study version of this CRF is found on page 32.

Bronchoscopy table= bronch

Visit Date: visit

1. Is the PaO2/FiO2 less than 80?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	bpfr
2. Is ETT size < 7.0?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	betts
3. Is there marked cardiovascular instability? <ul style="list-style-type: none"> • Acute ischemic heart disease (unstable angina, acute MI)? • Severe hypotension with a systolic BP < 90 mm Hg? • Ongoing ventricular cardiac dysrhythmias (SVT > 140 bpm, complex ventricular ectopy?) 	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	bcvin
4. Does patient have a known elevated ICP (sustained ICP greater than or equal to 20)?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	beicp
IF QUESTIONS 1-4 NO, PATIENT IS ELIGIBLE FOR BRONCHOALVEOLAR LAVAGE. OBTAIN FLUID ANALYSIS OF BAL.		
5. Cell count: <ul style="list-style-type: none"> • EXAMPLE: 250,000 = 2.5 x 10⁵ cells/mm³ 	<input type="text"/> x 10 [^] <input type="text"/> cells/mm ³	bcell1 scinote1
DIFFERENTIAL:		
6a. Alveolar macrophages:	<input type="text"/>	bdiff1
6b. PMNS:	<input type="text"/>	bdiff2
6c. Eosinophils:	<input type="text"/>	bdiff3
6d. Lymphocytes:	<input type="text"/>	bdiff4
6e. Other:	<input type="text"/>	bdiff5
7. Quantitative culture 1 count (if available):	<input type="text"/> x 10 [^] <input type="text"/> colony forming units/mL lavage fluid	quant1 scinote2
	<input type="radio"/> No Answer <input type="radio"/> Staph aureus (1) <input type="radio"/> Staph epidermidis (2) <input type="radio"/> Strep pneumoniae (3) <input type="radio"/> Enterococcus (4) <input type="radio"/> Other Gram Positive Cocci (5) <input type="radio"/> Pseudomonas species (6)	

table= bronch

<p>8. Organism 1:</p>	<ul style="list-style-type: none"> <input type="radio"/> Hemophilus influenza (7) <input type="radio"/> Other Gram Negative Rod (8) <input type="radio"/> B. catarhalis (9) <input type="radio"/> Other Gram Negative Cocci (10) <input type="radio"/> Candida species (11) <input type="radio"/> Torulopsis species (12) <input type="radio"/> Aspergillus species (13) <input type="radio"/> Varicella zoster (14) <input type="radio"/> Herpes simplex (15) <input type="radio"/> CMV (16) <input type="radio"/> Other virus (17) <input type="radio"/> Pneumocystis carinii (18) <input type="radio"/> Mycobacterium tuberculosis (19) <input type="radio"/> Other Mycobacterium (20) <input type="radio"/> Other organism (21) 	<p>borgn1</p>
<p>9. Quantitative culture 2 count (if available):</p>	<p><input type="text"/> x 10 ^ <input type="text"/> colony forming units/mL lavage fluid</p>	<p>quant4 scinote3</p>
<p>10. Organism 2:</p>	<ul style="list-style-type: none"> <input type="radio"/> No Answer <input type="radio"/> Staph aureus (1) <input type="radio"/> Staph epidermidis (2) <input type="radio"/> Strep pneumoniae (3) <input type="radio"/> Enterococcus (4) <input type="radio"/> Other Gram Positive Cocci (5) <input type="radio"/> Pseudomonas species (6) <input type="radio"/> Hemophilus influenza (7) <input type="radio"/> Other Gram Negative Rod (8) <input type="radio"/> B. catarhalis (9) <input type="radio"/> Other Gram Negative Cocci (10) <input type="radio"/> Candida species (11) <input type="radio"/> Torulopsis species (12) <input type="radio"/> Aspergillus species (13) <input type="radio"/> Varicella zoster (14) <input type="radio"/> Herpes simplex (15) <input type="radio"/> CMV (16) <input type="radio"/> Other virus (17) <input type="radio"/> Pneumocystis carinii (18) <input type="radio"/> Mycobacterium tuberculosis (19) <input type="radio"/> Other Mycobacterium (20) <input type="radio"/> Other organism (21) 	<p>borgn2</p>
<p>11. Quantitative culture 3 count (if available):</p>	<p><input type="text"/> x !0 ^ <input type="text"/> colony forming units/mL lavage fluid</p>	<p>quant7 scinote4</p>
	<ul style="list-style-type: none"> <input type="radio"/> No Answer <input type="radio"/> Staph aureus (1) 	

table= bronch

12. Organism 3:	<ul style="list-style-type: none"><input type="radio"/> Staph epidermidis (2)<input type="radio"/> Strep pneumoniae (3)<input type="radio"/> Enterococcus (4)<input type="radio"/> Other Gram Positive Cocci (5)<input type="radio"/> Pseudomonas species (6)<input type="radio"/> Hemophilus influenza (7)<input type="radio"/> Other Gram Negative Rod (8)<input type="radio"/> B. catarhalis (9)<input type="radio"/> Other Gram Negative Cocci (10)<input type="radio"/> Candida species (11)<input type="radio"/> Torulopsis species (12)<input type="radio"/> Aspergillus species (13)<input type="radio"/> Varicella zoster (14)<input type="radio"/> Herpes simplex (15)<input type="radio"/> CMV (16)<input type="radio"/> Other virus (17)<input type="radio"/> Pneumocystic carinii (18)<input type="radio"/> Mycobacterium tuberculosis (19)<input type="radio"/> Other Mycobacterium (20)<input type="radio"/> Other organism (21)
COLLECT BLOOD SAMPLE FOR STORAGE (CYTOKINES AND PROCOLLAGEN PEPTIDE III LEVEL); PROCESS BAL FOR STORAGE.	

borgn3

Brussels table= brussels

Visit Date: visit

24 HR WORST VALUE; FOR CPK, USE HIGHEST							
Date	Systolic BP (mm Hg)	PaO2/FiO2	Platelets x 1000	Creatinine (mg/dl)	Bilirubin (mg/dl)	CPK (units/L)	Vasopressor
<input type="text"/> Date	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input checked="" type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
Data Entry Grid							

startdat syspbbru bruspafi brusplat bruscrea brusbili bruscpk vasobrus

On Study Glasgow Coma and Neuro Exam

Visit Date: visit

table= glasgow

<p>1. Is patient on a sedative or neuromuscular blocker? (If yes, use best GCS estimate):</p>	<p><input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)</p>	<p>sedate</p>
<p>2. Eye opening score:</p>	<p><input type="radio"/> No Answer <input type="radio"/> Spontaneous (4) <input type="radio"/> To Voice (3) <input type="radio"/> To Pain (2) <input type="radio"/> None (1)</p>	<p>eye</p>
<p>3. Motor response score:</p>	<p><input type="radio"/> No Answer <input type="radio"/> Obeys commands (6) <input type="radio"/> Localizes to pain (5) <input type="radio"/> Flexor withdrawal (4) <input type="radio"/> Abnormal flexion (3) <input type="radio"/> Extension (2) <input type="radio"/> Flaccid (1)</p>	<p>motor</p>
<p>4. Verbal response score:</p>	<p><input type="radio"/> No Answer <input type="radio"/> Oriented [or appears oriented, if on ventilator] (5) <input type="radio"/> Confused [or questionably oriented, if on ventilator] (4) <input type="radio"/> Inappropriate [or generally unresponsive, if on ventilator] (3) <input type="radio"/> Incomprehensible (2) <input type="radio"/> None (1)</p>	<p>verbal</p>
<p>5. Total GCS:</p>	<p><input type="text"/></p>	<p>gcst</p>
<p>IF PATIENT ON NEUROMUSCULAR BLOCKERS LAST 24 HOURS --> FORM COMPLETE.</p>		
<p>6. Does patient follow commands?</p>	<p><input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)</p>	<p>cmds</p>
<p>7. Neck flexor?</p>	<p><input type="radio"/> No Answer <input type="radio"/> No contraction (1) <input type="radio"/> Trace contraction (2) <input type="radio"/> Active contraction against gravity (3) <input type="radio"/> Active movement against gravity and resistance (4) <input type="radio"/> Normal power (5)</p>	<p>nckflex</p>
<p>8. Neck extensor?</p>	<p><input type="radio"/> No Answer <input type="radio"/> No contraction (1) <input type="radio"/> Trace contraction (2) <input type="radio"/> Active contraction against gravity (3) <input type="radio"/> Active movement against gravity and resistance (4) <input type="radio"/> Normal power (5)</p>	<p>nckext</p>

table= glasgow

<p>9a. Leg flexor (leg lifting), right leg:</p>	<p> <input type="radio"/> No Answer <input type="radio"/> No contraction (1) <input type="radio"/> Trace contraction (2) <input type="radio"/> Active contraction against gravity (3) <input type="radio"/> Active movement against gravity and resistance (4) <input type="radio"/> Normal power (5) </p>	<p>lgflexrt</p>
<p>9b. Leg flexor (leg lifting), left leg:</p>	<p> <input type="radio"/> No Answer <input type="radio"/> No contraction (1) <input type="radio"/> Trace contraction (2) <input type="radio"/> Active contraction against gravity (3) <input type="radio"/> Active movement against gravity and resistance (4) <input type="radio"/> Normal power (5) </p>	<p>lgflexlt</p>
<p>10. Biceps deep tendon reflex:</p>	<p> <input type="radio"/> No Answer <input type="radio"/> Absent (0) <input type="radio"/> Diminished (1) <input type="radio"/> Normal (2) <input type="radio"/> Hyperactive (3) <input type="radio"/> Hyperactive with clonus (4) </p>	<p>bcpref</p>
<p>11. Achilles deep tendon reflex:</p>	<p> <input type="radio"/> No Answer <input type="radio"/> Absent (0) <input type="radio"/> Diminished (1) <input type="radio"/> Normal (2) <input type="radio"/> Hyperactive (3) <input type="radio"/> Hyperactive with clonus (4) </p>	<p>achref</p>
<p>12a. Has spontaneous upper extremity movement been observed in last 24 hours?</p>	<p> <input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) </p>	<p>athetupp</p>
<p>12b. Has spontaneous lower extremity movement been observed in last 24 hours?</p>	<p> <input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) </p>	<p>athetlow</p>
<p>13. Are fasciculations or fibrillations present?</p>	<p> <input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) </p>	<p>fasic</p>

NOTE: Baseline and On-Study Glasgow Coma data are all found in the same table. The Baseline version of this CRF is found on page 17.

On Study Monitoring and Medications

Visit Date: visit

table= medicati

<p>1. Does chart review suggest new infection this calendar day?</p> <ul style="list-style-type: none"> • If bacteremia, fill out Bacteremia form. • If septic shock, fill out Septic Shock form. • If specific site of infection identified, fill out infection form for that site. 	<p><input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)</p>	<p>chart2</p>
<p>2. Do clinicians suspect new nosocomial pneumonia?</p>	<p><input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)</p>	<p>newn2</p>
<p>INDICATE IF ANY OF THE FOLLOWING MEDICATIONS WERE ADMINISTERED DURING THIS CALENDAR DAY.</p>		
<p>3. Have sedatives or tranquilizers been administered?</p>	<p><input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)</p>	<p>segs</p>
<p>4. Have neuromuscular blocking agents been administered?</p>	<p><input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)</p>	<p>nmba</p>
<p>5. Have antifungal agents been administered?</p>	<p><input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)</p>	<p>antif</p>
<p>6. Has amphotericin been administered?</p>	<p><input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)</p>	<p>ampho</p>
<p>7a. Have aminoglycosides been administered? (if yes, specify below):</p>	<p><input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)</p>	<p>amino</p>
<p>7b. Aminoglycosides administered (check all that apply):</p>	<p><input type="checkbox"/> Gentamicin (1) <input type="checkbox"/> Tobramycin (2) <input type="checkbox"/> Amikacin (3) <input type="checkbox"/> Other Aminoglycosides (4)</p>	<p>amino12 amino13 amino14 amino15</p>
<p>8a. Have cephalosporins been administered? (if yes, specify below):</p>	<p><input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)</p>	<p>ceph</p>
<p>8b. Cephalosporins administered (check all that apply):</p>	<p><input type="checkbox"/> Cefazolin (1) <input type="checkbox"/> Cefotaxime (2) <input type="checkbox"/> Cefotetan (3) <input type="checkbox"/> Ceftazidime (4) <input type="checkbox"/> Ceftriaxone (5) <input type="checkbox"/> Cefuroxime (6) <input type="checkbox"/> Cefepime (7) <input type="checkbox"/> Other Cephalosporins (8)</p>	<p>ceph12 ceph13 ceph14 ceph15 ceph16 ceph17 ceph18 ceph19</p>
<p>9a. Have macrolides been administered? (if yes, specify below):</p>	<p><input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)</p>	<p>mac</p>
	<p><input type="checkbox"/> Azithromycin (1)</p>	<p>mac12 29</p>

table= medicati

9b. Macrolides administered (check all that apply):	<input type="checkbox"/> Clarithromycin (2) <input type="checkbox"/> Clindamycin (3) <input type="checkbox"/> Erythromycin (4)	mac13 mac14 mac15
10a. Have penicillins been administered? (if yes, specify below):	<input checked="" type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	pcn
10b. Penicillins administered (check all that apply):	<input type="checkbox"/> Ampicillin (1) <input type="checkbox"/> Ampicillin-Subactam (2) <input type="checkbox"/> Aztreonam (3) <input type="checkbox"/> Imipenam-Cilistatin (4) <input type="checkbox"/> Nafcillin (5) <input type="checkbox"/> Penicillin (6) <input type="checkbox"/> Piperacillin (7) <input type="checkbox"/> Ticarcillin (8) <input type="checkbox"/> Other Penicillins (9)	pcn12 pcn13 pcn14 pcn15 pcn16 pcn17 pcn18 pcn19 pcn20
11a. Have quinolones been administered? (if yes, specify below):	<input checked="" type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	quino
11b. Quinolones administered (check all that apply):	<input type="checkbox"/> Ciprofloxacin (1) <input type="checkbox"/> Ofloxacin (2) <input type="checkbox"/> Other Quinolones (3)	quino12 quino13 quino14
12. Vancomycin administered?	<input checked="" type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	vanco
13. Other antibiotics administered?	<input checked="" type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	oant
14. Antipsychotics administered?	<input checked="" type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	apsych
15. Antivirals administered?	<input checked="" type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	avrls
16a. Experimental therapies employed? (If yes, specify below):	<input checked="" type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	expt1
16b. If yes, select experimental therapies:	<input type="checkbox"/> Nitric Oxide (1) <input type="checkbox"/> Surfactant therapy (2) <input type="checkbox"/> Partial liquid ventilation (3) <input type="checkbox"/> ECMO (4) <input type="checkbox"/> IVOX (5) <input type="checkbox"/> HFV or HFO (6) <input type="checkbox"/> Prone positioning (7) <input type="checkbox"/> Inhaled PGI or PGE (8) <input type="checkbox"/> Intravenous PGI or PGE (9) <input type="checkbox"/> Other experimental therapy (10)	expt21 expt22 expt23 expt24 expt25 expt26 expt27 expt28 expt29 expt30

NOTE: Baseline and On-Study Medications data are all found in the same table. The Baseline version of this CRF is found on page 19.

On Study Ventilator Parameters table= vent

Visit Date: visit

IF ON POSITIVE PRESSURE VENT DURING REFERENCE PERIOD 0600-1000. IF > 1 VALUE, USE VALUES CLOSEST TO 0800. IF ABG NOT AVAIL IN REFERENCE PERIOD, USE CLOSEST TO REFERENCE PERIOD ON SAME CALENDAR DATE.	
1. Ventilator mode (all that apply)	
1a. SIMV?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
1b. Pressure support?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
1c. Assist/Control?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
1d. Pressure control?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
1e. PC IRV?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
1f. Other:	<input type="text"/>
2. Calculated delivered tidal volume (if on volume cycled mode):	<input type="text"/> ml
3. Pressure control level (if on pressure control ventilation):	<input type="text"/> cm H2O
4. Pressure support level (if on pressure support ventilation):	<input type="text"/> cm H2O
5. Set rate:	<input type="text"/> breaths/min
6. Total respiratory rate:	<input type="text"/> breaths/min
7. Total minute ventilation:	<input type="text"/> L/min
8. PEEP:	<input type="text"/> cm H2O
9. Plateau pressure (cm H2O, 0.5 sec end-inspiratory pause):	<input type="text"/> cm H2O
10. FiO2:	<input type="text"/>
11. PaO2 on current FiO2:	<input type="text"/> mm Hg
12. PaCO2 on current ventilator settings:	<input type="text"/> mm Hg
13. Arterial pH:	<input type="text"/>
14. SpO2 on current FiO2:	<input type="text"/> %
15. Static Thoracic Compliance:	<input type="text"/> mL/cm H2O/kg IBW
16. Patient position:	<input type="radio"/> No Answer <input type="radio"/> Supine (1) <input type="radio"/> Prone (2) <input type="radio"/> Other (3)

ventm1
ventm2
ventm3
ventm4
ventm5
ventm6
cdtv
pcl
psvp
srat
trespr
tmnvnt
peep
platp
fio2vent
pao2vent
paco2_vt
artph
sats
stc
pposit

NOTE: Baseline and On-Study Vent Parameters data are all found in the same table. The Baseline version of this CRF is found on page 21.

On Study Vital Signs [table= vitals](#)

Visit Date: [visit](#)

USE DATA FROM REFERENCE PERIOD 0600-1000. IF MORE THAN ONE VALUE, USE VALUE CLOSEST TO 0800. IF NOT AVAILABLE IN REFERENCE PERIOD, USE CLOSEST TO REFERENCE PERIOD ON SAME CALENDAR DAY.	
1. Heart Rate:	<input type="text"/> beats/min
2. Systolic blood pressure:	<input type="text"/> mm Hg
3. Diastolic blood pressure:	<input type="text"/> mm Hg
4. Temperature:	<input type="text"/> C <input type="text"/> F
ENTER LAB VALUES, IF AVAILABLE, FOR DAYS 7, 14, 21, AND 28.	
5. Hematocrit:	<input type="text"/> %
6. White blood cell count:	<input type="text"/> cells/mm ³
7. Glucose:	<input type="text"/> mg/dL
8. Amylase level:	<input type="text"/> units/L
NOTE: DRAW BLOOD FOR STORAGE ON DAY 7.	

hrate

sysbp

diasbp

ctemp ftemp

crit

wbcct

glucose

amylase

NOTE: Baseline and On-Study Vital Signs data are all found in the same table. The Baseline version of this CRF is found on page 22.

Specimen Collection [table= specimen](#)

Visit Date: [visit](#)

ATTACH COMMENT EXPLAINING REASON IF ANY BLOOD OR BAL SAMPLES WERE NOT COLLECTED.	
Day 0	
1a. Was blood drawn for storage on day 0?	<input checked="" type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
1b. If yes, give date blood taken for storage:	<input type="text"/> <input type="button" value="Date"/>
2a. Was BAL taken for storage on day 0?	<input checked="" type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
2b. If yes, give date of BAL collection for storage:	<input type="text"/> <input type="button" value="Date"/>
Day 7	
3a. Was blood drawn for storage on day 7?	<input checked="" type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
3b. Date blood taken for storage (date of day 7):	<input type="text"/> <input type="button" value="Date"/>
4a. Was BAL taken for storage on day 7?	<input checked="" type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
4b. If yes, give date BAL taken for storage (date of day 7):	<input type="text"/> <input type="button" value="Date"/>

bcyt

bcytdate

balp

baldate

bcyt1

bcytdate1

balp1

baldate2

Weaning table= weaning

Visit Date: visit

DURING THIS CALENDAR DAY																															
1. Was the patient permanently withdrawn from LaSRS?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) wdrawn																														
2a. Was study drug administered?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) drugadm																														
2b. Total dose of study drug administered this calendar day:	<input type="text"/> mg drugdose																														
3. Is study drug being tapered?	<input type="radio"/> No Answer <input type="radio"/> No (1) <input type="radio"/> Slow (2) <input type="radio"/> Rapid (3) taper																														
4. At 0600, patient on:	<input type="radio"/> No Answer wean1 <input type="radio"/> Volume Assist/Control Ventilation (1) NOTE: some wean4 entries have been modified to deidentify data <input type="radio"/> Pressure Support Ventilation (2) <input type="radio"/> Unassisted Breathing (3) <input type="radio"/> Other -- specify below (4)																														
4a. Other:	<input type="text"/> wean2																														
5. Did patient meet weaning evaluation criteria?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) <input type="radio"/> Not tried/Evaluated (3) weancrit																														
5a. If 5 is yes, did patient pass 5 minute CPAP trial?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) cpaptrl																														
6. Were there any attempts to wean PS by 5 cm H2O?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No -- specify reason below (2) wean3																														
6i. If no, why not?	<input type="text"/> wean4																														
WEANING HISTORY: Record initial and subsequent pressure support levels along with their corresponding starting times each time the pressure support level is changed.																															
	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 25%;"></th> <th style="width: 25%;">Pressure Support Level (cm H2O)</th> <th style="width: 25%;">Time (hh:mm)</th> <th style="width: 25%;"></th> <th style="width: 25%;">Pressure Support Level (cm H2O)</th> <th style="width: 25%;">Time (hh:mm)</th> </tr> </thead> <tbody> <tr> <td>6a.</td> <td><input type="text" value="weanhx1"/></td> <td><input type="text" value="weanhx2"/></td> <td>6b.</td> <td><input type="text" value="weanhx3"/></td> <td><input type="text" value="weanhx4"/></td> </tr> <tr> <td>6c.</td> <td><input type="text" value="weanhx5"/></td> <td><input type="text" value="weanhx6"/></td> <td>6d.</td> <td><input type="text" value="weanhx7"/></td> <td><input type="text" value="weanhx8"/></td> </tr> <tr> <td>6e.</td> <td><input type="text" value="weanhx9"/></td> <td><input type="text" value="weanhx10"/></td> <td>6f.</td> <td><input type="text" value="weanhx11"/></td> <td><input type="text" value="weanhx12"/></td> </tr> <tr> <td>6g.</td> <td><input type="text" value="weanhx13"/></td> <td><input type="text" value="weanhx14"/></td> <td>6h.</td> <td><input type="text" value="weanhx15"/></td> <td><input type="text" value="weanhx16"/></td> </tr> </tbody> </table>		Pressure Support Level (cm H2O)	Time (hh:mm)		Pressure Support Level (cm H2O)	Time (hh:mm)	6a.	<input type="text" value="weanhx1"/>	<input type="text" value="weanhx2"/>	6b.	<input type="text" value="weanhx3"/>	<input type="text" value="weanhx4"/>	6c.	<input type="text" value="weanhx5"/>	<input type="text" value="weanhx6"/>	6d.	<input type="text" value="weanhx7"/>	<input type="text" value="weanhx8"/>	6e.	<input type="text" value="weanhx9"/>	<input type="text" value="weanhx10"/>	6f.	<input type="text" value="weanhx11"/>	<input type="text" value="weanhx12"/>	6g.	<input type="text" value="weanhx13"/>	<input type="text" value="weanhx14"/>	6h.	<input type="text" value="weanhx15"/>	<input type="text" value="weanhx16"/>
	Pressure Support Level (cm H2O)	Time (hh:mm)		Pressure Support Level (cm H2O)	Time (hh:mm)																										
6a.	<input type="text" value="weanhx1"/>	<input type="text" value="weanhx2"/>	6b.	<input type="text" value="weanhx3"/>	<input type="text" value="weanhx4"/>																										
6c.	<input type="text" value="weanhx5"/>	<input type="text" value="weanhx6"/>	6d.	<input type="text" value="weanhx7"/>	<input type="text" value="weanhx8"/>																										
6e.	<input type="text" value="weanhx9"/>	<input type="text" value="weanhx10"/>	6f.	<input type="text" value="weanhx11"/>	<input type="text" value="weanhx12"/>																										
6g.	<input type="text" value="weanhx13"/>	<input type="text" value="weanhx14"/>	6h.	<input type="text" value="weanhx15"/>	<input type="text" value="weanhx16"/>																										
7. Did patient tolerate a trial of spontaneous breathing for more than two hours?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) <input type="radio"/> Not tried/Evaluated (3) wean5																														
8. Did patient complete 48 hours of unassisted breathing on this calendar day?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) wean6																														

Deep Tissue Abscess [table= abscess](#)

Visit Date: [visit](#)

THIS FORM IS TO BE COMPLETED FOR ABDOMINAL OR OTHER DEEP TISSUE ABSCESSSES	
1. Date of diagnosis of abscess:	<input type="text"/> <input type="button" value="Date"/>
2. Organism:	<ul style="list-style-type: none"> <input type="radio"/> No Answer <input type="radio"/> Staph aureus (1) <input type="radio"/> Staph epidermidis (2) <input type="radio"/> Strep pneumoniae (3) <input type="radio"/> Enterococcus (4) <input type="radio"/> Other Gram Positive Coccus (5) <input type="radio"/> Pseudomonas species (6) <input type="radio"/> Hemophilus influenza (7) <input type="radio"/> Other Gram Negative Rod (8) <input type="radio"/> B. catarhalis (9) <input type="radio"/> Other Gram Negative Cocci (10) <input type="radio"/> Candida species (11) <input type="radio"/> Torulopsis species (12) <input type="radio"/> Aspergillus species (13) <input type="radio"/> Varicella zoster (14) <input type="radio"/> Herpes simplex (15) <input type="radio"/> CMV (16) <input type="radio"/> Other virus (17) <input type="radio"/> None identified/obtained (18) <input type="radio"/> Other organism (19)
3. Site of infection/abscess:	<ul style="list-style-type: none"> <input type="radio"/> No Answer <input type="radio"/> Hepatic abscess (1) <input type="radio"/> Splenic abscess (2) <input type="radio"/> Pericolonic abscess (3) <input type="radio"/> Pancreatic abscess (4) <input type="radio"/> Cholecystitis (5) <input type="radio"/> Myositis (6) <input type="radio"/> Other (7)
<p>IF SEPTIC SHOCK DEVELOPED AS A CONSEQUENCE OF THIS INFECTION, FILL OUT SEPTIC SHOCK FORM (IF NOT ALREADY DONE). IF BLOOD CULTURES POSITIVE, FILL OUT BACTEREMIA FORM.</p>	

dtisu1

dtisu2

dtisu3

Bacteremia `table= bacter`

Visit Date: `visit`

Date of blood culture	Time of blood draw	Organism recovered
<input data-bbox="159 359 342 401" type="text"/> <input data-bbox="342 359 435 401" type="button" value="Date"/> <code>startdat</code>	<input data-bbox="690 359 849 401" type="text"/> hh:mm <code>btime1</code>	<input type="radio"/> No Answer <input type="radio"/> Staph aureus (1) <input type="radio"/> Staph epidermidis (2) <input type="radio"/> Strep pneumoniae (3) <input type="radio"/> Enterococcus (4) <input type="radio"/> Other Gram Positive Cocci (5) <input type="radio"/> Pseudomonas species (6) <input type="radio"/> Hemophilus influenza (7) <input type="radio"/> Other Gram Negative Rod (8) <input type="radio"/> B. catarhalis (9) <input type="radio"/> Other Gram Negative Cocci (10) <input type="radio"/> Candida species (11) <input type="radio"/> Torulopsis species (12) <input type="radio"/> Aspergillus species (13) <input type="radio"/> Varicella zoster (14) <input type="radio"/> Herpes simplex (15) <input type="radio"/> CMV (16) <input type="radio"/> Other virus (17) <input type="radio"/> Other organism (18)

`bacorg1`

Empyema table= empyema

Visit Date: visit

1. Date of diagnosis of empyema:	<input type="text"/> <input type="button" value="Date"/>
2. Organism:	<ul style="list-style-type: none"><input type="radio"/> No Answer<input type="radio"/> Staph aureus (1)<input type="radio"/> Staph epidermidis (2)<input type="radio"/> Strep pneumoniae (3)<input type="radio"/> Enterococcus (4)<input type="radio"/> Other Gram Positive Coccus (5)<input type="radio"/> Pseudomonas species (6)<input type="radio"/> Hemophilus influenza (7)<input type="radio"/> Other Gram Negative Rod (8)<input type="radio"/> B. catarhalis (9)<input type="radio"/> Other Gram Negative Cocci (10)<input type="radio"/> Candida species (11)<input type="radio"/> Torulopsis species (12)<input type="radio"/> Aspergillus species (13)<input type="radio"/> Varicella zoster (14)<input type="radio"/> Herpes simplex (15)<input type="radio"/> CMV (16)<input type="radio"/> Other virus (17)<input type="radio"/> None identified/obtained (18)<input type="radio"/> Other organism (19)
<p align="center">IF SEPTIC SHOCK DEVELOPED AS A CONSEQUENCE OF THIS INFECTION, FILL OUT SEPTIC SHOCK FORM (IF NOT DONE ALREADY). IF BLOOD CULTURES POSITIVE, FILL OUT BACTEREMIA FORM.</p>	

empye1

empye2

Fungal Infection table= fungal

Visit Date: visit

1a. Is blood culture positive for yeast infection? (If yes, give date below):	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	fungl1
1b. Date of positive culture:	<input type="text"/> <input type="button" value="Date"/>	fungl2
2a. Is there evidence of deep tissue infection? (endophthalmitis, hepatic/splenic abscesses, etc.); If yes, give date below:	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	fungl3
2b. Date of diagnosis of infection:	<input type="text"/> <input type="button" value="Date"/>	fungl4
3a. Does patient have unexplained fever with 3 sites of colonization? (If yes, give date below):	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	fungl5
3b. Date of diagnosis:	<input type="text"/> <input type="button" value="Date"/>	fungl6
4a. Does patient have oral or mucosal candidiasis? (If yes, give date below):	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	fungl7
4b. Date of diagnosis of candidiasis:	<input type="text"/> <input type="button" value="Date"/>	fungl8
5. Fungal infection causative organism:	<input type="radio"/> No Answer <input type="radio"/> Candida species (1) <input type="radio"/> Torulopsis species (2) <input type="radio"/> Aspergillus species (3) <input type="radio"/> Other (4)	fungl9
IF 1a, 2a, OR 3a ARE ANSWERED YES, BEGIN RAPID TAPER.		
IF SEPTIC SHOCK DEVELOPED AS A CONSEQUENCE OF THIS INFECTION, FILL OUT SEPTIC SHOCK FORM (IF NOT ALREADY DONE).		

Meningitis table= mening

Visit Date: visit

1. Date of diagnosis of meningitis:	<input type="text"/> Date
2. Organism recovered from CSF:	<ul style="list-style-type: none"> <input type="radio"/> No Answer <input type="radio"/> Neiseria meningiditis (1) <input type="radio"/> Strep pneumoniae (2) <input type="radio"/> Hemophilus influenza (3) <input type="radio"/> Other Gram Negative Rod (4) <input type="radio"/> Staph aureus (5) <input type="radio"/> Other organism (6)
IF SEPTIC SHOCK DEVELOPED AS A CONSEQUENCE OF THIS INFECTION, FILL OUT SEPTIC SHOCK FORM (IF NOT ALREADY DONE). IF BLOOD CULTURES POSITIVE, FILL OUT BACTEREMIA FORM.	

mengt1

mengt2

Peritonitis table= periton

Visit Date: visit

<p>THIS FORM IS TO BE COMPLETED FOR PERITONITIS <i>NOT</i> ASSOCIATED WITH PERITONEAL DIALYSIS. PERITONITIS IS DEFINED AS A POSITIVE GRAM STAIN OR CULTURE OF PERITONEAL FLUID WITH > 250 PMNs/mL IN PERITONEAL FLUID OR FREE PERITONEAL AIR WITH BACTEREMIA.</p>	
1. Date of diagnosis of peritonitis:	<input type="text"/> <input type="button" value="Date"/>
2. Peritoneal fluid culture:	<ul style="list-style-type: none"> <input type="radio"/> No Answer <input type="radio"/> Staph aureus (1) <input type="radio"/> Staph epidermidis (2) <input type="radio"/> Strep pneumoniae (3) <input type="radio"/> Enterococcus (4) <input type="radio"/> Other Gram Positive Coccus (5) <input type="radio"/> Pseudomonas species (6) <input type="radio"/> Hemophilus influenza (7) <input type="radio"/> Other Gram Negative Rod (8) <input type="radio"/> B. catarhalis (9) <input type="radio"/> Other Gram Negative Cocci (10) <input type="radio"/> Candida species (11) <input type="radio"/> Torulopsis species (12) <input type="radio"/> Aspergillus species (13) <input type="radio"/> Varicella zoster (14) <input type="radio"/> Herpes simplex (15) <input type="radio"/> CMV (16) <input type="radio"/> Other virus (17) <input type="radio"/> None identified/obtained (18) <input type="radio"/> Other (19)
<p>IF SEPTIC SHOCK DEVELOPED AS A CONSEQUENCE OF THIS INFECTION, FILL OUT SEPTIC SHOCK FORM (IF NOT ALREADY DONE). IF BLOOD CULTURES POSITIVE, FILL OUT BACTEREMIA FORM.</p>	

pertn1

pertn2

Pneumonia table= pneum

Visit Date: visit

1. Date of pneumonia diagnosis:	<input type="text"/> <input type="button" value="Date"/>	pneum1
2. WITHIN A 48 HOUR PERIOD, DID THE PATIENT HAVE:		
2a. Chest radiograph showing new infiltrate that has persisted for 48 hours?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	pneum9
2b. New fever, hypothermia, leukocytosis, or leukopenia?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	pneum2
3. Was an endotracheal aspirate sent for gram stain?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	pneum3
4. Was an endotracheal aspirate sent for culture?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	pneum4
5a. Was there bacteriological confirmation of episode of suspected pneumonia?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	pneum5
5b. Organism 1:	<input type="radio"/> No Answer <input type="radio"/> Staph aureus (1) <input type="radio"/> Staph epidermidis (2) <input type="radio"/> Strep pneumoniae (3) <input type="radio"/> Enterococcus (4) <input type="radio"/> Other Gram Positive Coccus (5) <input type="radio"/> Pseudomonas species (6) <input type="radio"/> Hemophilus influenza (7) <input type="radio"/> Other Gram Negative Rod (8) <input type="radio"/> B. catarhalis (9) <input type="radio"/> Other Gram Negative Cocci (10) <input type="radio"/> Candida species (11) <input type="radio"/> Torulopsis species (12) <input type="radio"/> Aspergillus species (13) <input type="radio"/> Varicella zoster (14) <input type="radio"/> Herpes simplex (15) <input type="radio"/> CMV (16) <input type="radio"/> Other virus (17) <input type="radio"/> Mycobacterium tuberculosis (18) <input type="radio"/> Other Mycobacterium (19) <input type="radio"/> Pneumocystic carinii (20) <input type="radio"/> Other organism (21)	pneum6
	<input type="radio"/> No Answer <input type="radio"/> Staph aureus (1) <input type="radio"/> Staph epidermidis (2) <input type="radio"/> Strep pneumoniae (3)	

table= pneum

5c. Organism 2 (if more than one present):	<ul style="list-style-type: none"><input type="radio"/> Enterococcus (4)<input type="radio"/> Other Gram Positive Coccus (5)<input type="radio"/> Pseudomonas species (6)<input type="radio"/> Hemophilus influenza (7)<input type="radio"/> Other Gram Negative Rod (8)<input type="radio"/> B. catarhalis (9)<input type="radio"/> Other Gram Negative Cocci (10)<input type="radio"/> Candida species (11)<input type="radio"/> Torulopsis species (12)<input type="radio"/> Aspergillus species (13)<input type="radio"/> Varicella zoster (14)<input type="radio"/> Herpes simplex (15)<input type="radio"/> CMV (16)<input type="radio"/> Other virus (17)<input type="radio"/> Mycobacterium tuberculosis (18)<input type="radio"/> Other Mycobacterium (19)<input type="radio"/> Pneumocystis carinii (20)<input type="radio"/> Other organism (21)
5d. Organism 3 (if more than two present):	<ul style="list-style-type: none"><input type="radio"/> No Answer<input type="radio"/> Staph aureus (1)<input type="radio"/> Staph epidermidis (2)<input type="radio"/> Strep pneumoniae (3)<input type="radio"/> Enterococcus (4)<input type="radio"/> Other Gram Positive Coccus (5)<input type="radio"/> Pseudomonas species (6)<input type="radio"/> Hemophilus influenza (7)<input type="radio"/> Other Gram Negative Rod (8)<input type="radio"/> B. catarhalis (9)<input type="radio"/> Other Gram Negative Cocci (10)<input type="radio"/> Candida species (11)<input type="radio"/> Torulopsis species (12)<input type="radio"/> Aspergillus species (13)<input type="radio"/> Varicella zoster (14)<input type="radio"/> Herpes simplex (15)<input type="radio"/> CMV (16)<input type="radio"/> Other virus (17)<input type="radio"/> Mycobacterium tuberculosis (18)<input type="radio"/> Other Mycobacterium (19)<input type="radio"/> Pneumocystis carinii (20)<input type="radio"/> Other organism (21)
IF SEPTIC SHOCK DEVELOPED AS A CONSEQUENCE OF THIS INFECTION, FILL OUT SEPTIC SHOCK FORM (IF NOT ALREADY DONE).	

pneum7

pneum8

Septic Shock table= septic

Visit Date: visit

FILL OUT THIS FORM FOR EACH EPISODE OF SEPTIC SHOCK.	
<p>1a. Were two or more of the following SIRS criteria present?</p> <ul style="list-style-type: none"> • Temperature > 38 C or < 36 C <i>OR</i> • Heart rate > 90 beats/min <i>OR</i> • Respiratory rate > 20 breaths/min or PaCO₂ < 32 mm Hg (if on unassisted breathing) <i>OR</i> • WBC > 12,000 or < 4,000 or > 10% immature (bands) 	<p><input checked="" type="radio"/> No Answer <input checked="" type="radio"/> Yes (1) <input type="radio"/> No (2)</p>
1b. If yes, give date of SIRS onset:	<input type="text"/> <input type="button" value="Date"/>
<p>ONE OR MORE OF THE FOLLOWING SHOCK CRITERIA (2A-2C) MUST BE PRESENT FOR >= 2 CONSECUTIVE HOURS DESPITE FLUID RESUSCITATION TO MEET SHOCK CRITERIA. SELECT ALL THAT APPLY.</p>	
2a. Systolic BP less than 90 mm Hg?	<p><input checked="" type="radio"/> No Answer <input checked="" type="radio"/> Yes (1) <input checked="" type="radio"/> No (2)</p>
2b. BP reduction greater than or equal to 40 mm Hg from baseline?	<p><input checked="" type="radio"/> No Answer <input checked="" type="radio"/> Yes (1) <input checked="" type="radio"/> No (2)</p>
2c. Pressor requirement to maintain BP?	<p><input checked="" type="radio"/> No Answer <input checked="" type="radio"/> Yes (1) <input checked="" type="radio"/> No (2)</p>
2d. Date first shock criteria met:	<input type="text"/> <input type="button" value="Date"/>
3. Was the primary site of infection identified? (If yes, give site below):	<p><input checked="" type="radio"/> No Answer <input checked="" type="radio"/> Yes (1) <input checked="" type="radio"/> No (2)</p>
3a. Primary site of infection:	<p> <input checked="" type="radio"/> No Answer <input type="radio"/> Pneumonia (1) <input type="radio"/> Peritonitis (2) <input type="radio"/> Wound infection (3) <input type="radio"/> Meningitis (4) <input type="radio"/> Empyema (5) <input type="radio"/> Biliary tract (6) <input type="radio"/> Abdominal abscess (7) <input type="radio"/> C. difficile colitis (8) <input type="radio"/> Urinary tract (9) <input type="radio"/> Vascular line (10) <input type="radio"/> Peritonitis on dialysis (11) <input type="radio"/> Sinusitis (12) <input type="radio"/> Skin infection (13) </p>

septic1

septic2

septic3

septic4

septic5

septic6

septic7

septic8

table= septic

	<input type="radio"/> Septic arthritis (14) <input type="radio"/> Other (15)
4a. Did the shock episode resolve? (If yes, give date below):	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
4b. Date of shock resolution:	<input type="text"/> <input type="button" value="Date"/>

septic9

septic10

Viral Infection table= viral

Visit Date: visit

THIS FORM IS TO BE COMPLETED FOR DISSEMINATED VIRAL INFECTIONS.	
1. Date of diagnosis of viral infection:	<input type="text"/> <input type="button" value="Date"/>
2a. Causative organism 1:	<input type="radio"/> No Answer <input type="radio"/> Herpes simplex (1) <input type="radio"/> Varicella zoster (2) <input type="radio"/> CMV (3) <input type="radio"/> Other (4)
2b. Causative organism 2 (if more than one virus present):	<input type="radio"/> No Answer <input type="radio"/> Herpes simplex (1) <input type="radio"/> Varicella zoster (2) <input type="radio"/> CMV (3) <input type="radio"/> Other (4)
IF SEPTIC SHOCK DEVELOPED AS A CONSEQUENCE OF THIS INFECTION, FILL OUT SEPTIC SHOCK FORM (IF NOT ALREADY DONE).	

viral1

viral2

viral3

Wound Infection table= wound

Visit Date: visit

THIS FORM IS TO BE COMPLETED FOR WOUND INFECTION REQUIRING EXTENSIVE DEBRIDEMENT AND/OR HEALING BY SECONDARY INTENTION.	
1. Date of diagnosis of wound infection:	<input type="text"/> <input type="button" value="Date"/>
2. Wound culture causative organism:	<ul style="list-style-type: none"> <input type="radio"/> No Answer <input type="radio"/> Staph aureus (1) <input type="radio"/> Staph epidermidis (2) <input type="radio"/> Strep pneumoniae (3) <input type="radio"/> Enterococcus (4) <input type="radio"/> Other Gram Positive Coccus (5) <input type="radio"/> Pseudomonas species (6) <input type="radio"/> Hemophilus influenza (7) <input type="radio"/> Other Gram Negative Rod (8) <input type="radio"/> B. catarhalis (9) <input type="radio"/> Other Gram Negative Cocci (10) <input type="radio"/> Candida species (11) <input type="radio"/> Torulopsis species (12) <input type="radio"/> Aspergillus species (13) <input type="radio"/> Varicella zoster (14) <input type="radio"/> Herpes simplex (15) <input type="radio"/> CMV (16) <input type="radio"/> Other virus (17) <input type="radio"/> None identified/obtained (18) <input type="radio"/> Other organism (19)
IF SEPTIC SHOCK DEVELOPED AS A CONSEQUENCE OF THIS INFECTION, FILL OUT SEPTIC SHOCK FORM (IF NOT ALREADY DONE). IF BLOOD CULTURES POSITIVE, FILL OUT BACTEREMIA FORM.	

wound1

wound2

Other Infection table= oth_inf

Visit Date: visit

1a. C. difficile colitis? (If yes, give date below):	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	othrin1
1b. Date of C. difficile colitis diagnosis:	<input type="text"/> <input type="button" value="Date"/>	othrin2
2a. Indwelling vascular line infection? (If yes, give date below):	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	othrin3
2b. Date of vascular line infection diagnosis:	<input type="text"/> <input type="button" value="Date"/>	othrin4
3a. Peritonitis (on peritoneal dialysis)? (If yes, give date below):	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	othrin5
3b. Date of peritonitis diagnosis:	<input type="text"/> <input type="button" value="Date"/>	othrin6
4a. Sinus infection? (If yes, give date below):	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	othrin7
4b. Date of sinus infection diagnosis:	<input type="text"/> <input type="button" value="Date"/>	othrin8
5a. Skin infection? (If yes, give date below):	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	othrin9
5b. Date of skin infection diagnosis:	<input type="text"/> <input type="button" value="Date"/>	othrin10
6a. Septic arthritis? (If yes, give date below):	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	othrin11
6b. Date of septic arthritis diagnosis:	<input type="text"/> <input type="button" value="Date"/>	othrin12
7a. Urinary tract infection? (If yes, give date below):	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	othrin13
7b. Date of UTI diagnosis:	<input type="text"/> <input type="button" value="Date"/>	othrin14
8a. Other infection? (If yes, give date below):	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	othrin15
8b. Date of diagnosis of other infection:	<input type="text"/> <input type="button" value="Date"/>	othrin16
IF BLOOD CULTURES POSITIVE, FILL OUT BACTEREMIA FORM. IF SEPTIC SHOCK, FILL OUT SEPTIC SHOCK FORM.		

Myopathy table= myopathy

Visit Date: visit

FILL OUT THIS FORM ONCE FOR EACH PATIENT. FOR THOSE PATIENTS WITH EVIDENCE OF MYOPATHY, MYOSITIS, NEUROMYOPATHY, UNEXPLAINED MUSCLE WEAKNESS, OR PARALYSIS FOLLOW UNTIL RESOLUTION OR HOSPITAL DISCHARGE TO DAY 60.	
1. Chart review reveals evidence (diagnosis or mention of) for any of the following: (Indicate all that apply)	
1a. Myopathy?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
1b. Myositis?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
1c. Neuropathy?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
1d. Muscle weakness?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
1e. Paralysis?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
2. If there is evidence of conditions A-E above, specify distribution (mark all that apply)	
2a. Upper extremity	<input type="checkbox"/>
2b. Lower extremity	<input type="checkbox"/>
2c. Neck	<input type="checkbox"/>
2d. Unknown	<input type="checkbox"/>
3. Date of onset of clinical abnormality (if known):	<input type="text"/> <input type="button" value="Date"/>
4. Duration of clinical abnormality in days (if known):	<input type="text"/>
5. Evidence of sensory deficit?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2) <input type="radio"/> Unknown (3)

chart1

chart3

chart4

chart5

chart6

locate1

locate2

locate3

locate4

dtonset

duratabn

sensdef

Study Termination `table= study_te`

Visit Date: `visit`

<p>COMPLETE THIS FORM WHEN THE PATIENT: (1) GOES HOME WITH UNASSISTED BREATHING OR SUSTAINS UNASSISTED BREATHING AT HOME FOR MORE THAN 48 HOURS OR (2) DIES (WHICHEVER COMES FIRST).</p> <p>FOR PATIENTS ALIVE AFTER DAY 28 WHO HAVE NOT BEEN DISCHARGED HOME OR ARE ON ASSISTED BREATHING, CHECK ON THE PATIENT'S STATUS AT INTERVALS OF AT MOST 30 DAYS UNTIL 1 OR 2 OCCURS OR THE PATIENT SURVIVES 60 DAYS AT ANY LOCATION WITH OR WITHOUT ASSISTED BREATHING.</p>	
Visit date (date of termination from study):	<input type="text"/> <input type="button" value="Date"/>
1. Patient status:	<input type="radio"/> No Answer <input type="radio"/> Home with unassisted breathing (1) <input type="radio"/> Dead prior to discharge home with unassisted breathing or dead before UAB at home for 48 hrs. (2) <input type="radio"/> Other (3)
1a. If 1, give date patient was discharged home on unassisted breathing:	<input type="text"/> <input type="button" value="Date"/>
1b. If 2, give date of death:	<input type="text"/> <input type="button" value="Date"/>
1c. If 3, give date of last patient contact:	<input type="text"/> <input type="button" value="Date"/>
2. Was patient able to sustain continuous unassisted breathing for at least 48 hrs during first 28 days?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
2a. If yes, give calendar date of first period of unassisted breathing lasting greater than or equal to 48 hours:	<input type="text"/> <input type="button" value="Date"/>
3. Did patient return to assisted breathing during the first 28 days after achieving unassisted breathing?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
3a. If yes, give number of calendar days on which the patient required assisted breathing between date in 2a and day 28:	<input type="text"/>
4. Was patient discharged alive from ICU during first 28 days of enrollment?	<input type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)
4a. If yes, give date of discharge from ICU:	<input type="text"/> <input type="button" value="Date"/>
5. Did patient return to ICU during	

`visit`

`status`

`st1dt`

`st2dt`

`st3dt`

`sust28`

`unassist`

`assist`

`asdays`

`icu`

`tm_icudt`

table= study_te

first 28 days of enrollment?	<input checked="" type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	ricu
5a. If yes, give number of calendar days on which the patient received any ICU care between date in 4a and day 28:	<input type="text"/>	ricudays
6. Was the patient discharged alive from the study hospital?	<input checked="" type="radio"/> No Answer <input type="radio"/> Yes (1) <input type="radio"/> No (2)	alive
6a. If yes, give date of study hospital discharge:	<input type="text"/> <input type="button" value="Date"/>	alivedt