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FILL OUT FOR ALL PATIENTS WITH ARDS >= 7 DAYS AND <= 28 DAYS WHO MEET SCREENING CRITERIA IN DESIGNATED ICUs		

1. Has patient had all of the following within a 24 hour interval?

- PaO2/FiO2 <= 200 mm Hg (if altitude > 1000m use (PaO2/FiO2) x (Pbar/760))
- Bilateral infiltrates
- Receiving positive pressure ventilation via endotracheal tube
- No clinical evidence of left atrial hypertension (if measured pulmonary arterial wedge pressure <= 18 mm Hg)

○ No Answer   ○ Yes (1)   ○ No (2)   screen1

2. Date these criteria exist simultaneously (date of ARDS onset): [   ] [Date]   adate

onset

3. Has patient had ARDS for greater than or equal to 7 and less than or equal to 28 days since onset?   ○ No Answer   ○ Yes (1)   ○ No (2)

4. Gender: ○ No Answer   ○ Male (1)   ○ Female (2)   gender

ethnic

NOTE: this item has been modified to deindentify the data. All responses of 3,4,5, or 6 were grouped to show a response of 6.

5. Ethnicity:
○ No Answer
○ White, not of Hispanic Origin (1)
○ Black, not of Hispanic Origin (2)
○ Hispanic (3)
○ Asian/Pacific Islander (4)
○ American Indian/Alaskan Native (5)
○ Other (6)

NOTE: ages greater than 89 are reported as 89 to deidentify data

6. Age: [   ]   age

loc

7. Hospital location:
○ No Answer
○ MICU (1)
○ SICU (2)
○ Cardiac SICU (3)
○ CCU (4)
○ Neuro ICU (5)
○ Burn (6)
○ Trauma (7)
○ Cancer Unit (8)
○ MICU/SICU (9)
○ Other (10)

8. Lung Injury Category

8a. Trauma: ○ No Answer   ○ Secondary (2)   ○ Primary (1)   trauma

2

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

ENTER QUALIFYING CRITERIA (FOR THOSE ENROLLED) OBTAINED DURING

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:	_____ mm Hg	screen2
13. FiO2:	_____	screen3
15. PEEP:	_____ cm H2O	screen5

Enrollment Criteria   table= enrollme   **Visit Date:**   visit

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

not committed to full support?	◉ No Answer ○ Yes (1) ○ 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):	◉ No Answer ○ Yes (1) ○ No (2)	scld

CHILD-PUGH SCORE: (11a-11e)
NOTE: FOR 11B USE FOLLOWING:

- **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?	◉ No Answer ○ Tense (3) ○ Present (2) ○ None (1)	asci
11b. Does the patient have encephalopathy?	◉ No Answer ○ Grade III or IV (3) ○ Grade I or II (2) ○ None (1)	ence
11c. Bilirubin (mg/dl):	◉ No Answer ○ [>3] (3) ○ [2-3] (2) ○ [<2] (1)	bili
11d. Albumin (g/dl):	◉ No Answer ○ [<2.8] (3) ○ [2.8-3.5] (2) ○ [>3.5] (1)	alb
11e. Prothrombin Time (sec. prolonged):	◉ No Answer ○ [>10] (3) ○ [5-10] (2) ○ [1-4] (1)	prot
11f. Total Child-Pugh Score:	[ ]	pugh
12. Has the patient had a transplant?		

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

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

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

METATRIAL

1. Date of adverse event:	[ ] [Date]	**aevent1**
2a. Specify adverse event:	⦿ No Answer ○ Uncontrolled hyperglycemia (1) ○ Wound dehiscence (2) ○ Acute psychosis (3) ○ Acute pancreatitis (4) ○ Other adverse event [specify below] (5) ○ 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:	⦿ No Answer ○ Mild (1) ○ Moderate (2) ○ Severe (3)	**aevent5**
5. Did AE require therapeutic intervention to avoid permanent impairment?	⦿ No Answer ○ Yes (1) ○ No (2)	**aevent6**
6. Was the patient in immediate risk of death due to adverse event?	⦿ No Answer ○ Yes (1) ○ No (2)	**aevent7**
7. Did patient die as a result of adverse event?	⦿ No Answer ○ Yes (1) ○ No (2)	**aevent8**
8. Was the event unexpected in ARDS or more severe/frequent than expected in ARDS?	⦿ No Answer ○ Yes (1) ○ No (2) ○ Unknown (3)	**aevent9**
9. Causal relationship to study drug?	⦿ No Answer ○ Definitely associated (1) ○ Probably associated (2) ○ Possible association (3) ○ Probably not associated (4) ○ Definitely not associated (5) ○ Uncertain association (6)	**aevent10**
10. Was study drug discontinued as a result of this event?	⦿ No Answer ○ Yes (1) ○ No (2)	**aevent11**
11a. Outcome to date:	⦿ No Answer ○ Recovered -- give date of recovery below: (1) ○ AE present, no treatment (2) ○ AE present, being treated (3) ○ Residual effect, no treatment (4) ○ Residual effect, being treated (5) ○ Deceased (6)	**aevent12**

11b. Date of recovery:	[_____] [Date]	aevent13
12a. Final outcome of this adverse event:	◉ No Answer ○ Recovered -- give date of recovery below: (1) ○ AE present, no treatment (2) ○ AE present, being treated (3) ○ Residual effect, no treatment (4) ○ Residual effect, being treated (5) ○ Deceased as a result of adverse effect (6)	aevent14
12b. Date of recovery:	[_____] [Date]	aevent15

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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?
				○ No Answer ◉ Yes (1) ○ No (2)

　　fio2　　　　　　　pao2　　　　　　　paco2　　　　　　ph　　　　　　　intubat

APACHE III Demographics table= apache_d   **Visit Date:** visit

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

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table= apache_d

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

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APACHE III Physiology   table= apache_p   **Visit Date:**   visit

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

19. Amylase:	amyll units/L	amylh units/L
20. Chloride:	chlorl mEq/L	chlorh mEq/L

Chest X-Ray   table= chest_xr   **Visit Date:**   visit

METΛTRIAL

USE MOST RECENT CXR PRIOR TO TIME OF ENROLLMENT.		
1. Radiographic Lung Injury Score (# of quadrants):	[ ]	radlis
2. Barotrauma:		
2a. Pneumothoraces:	◉ No Answer ○ Right (1) ○ Left (2) ○ Bilateral (3) ○ None (4)	baro1
2b. Subcutaneous emphysema:	◉ No Answer ○ Yes (1) ○ No (2)	baro2
2c. Pneumomediastinum:	◉ No Answer ○ Yes (1) ○ No (2)	baro3
2d. Pneumatoceles > 2 cm diameter:	◉ No Answer ○ Right (1) ○ Left (2) ○ Bilateral (3) ○ None (4)	baro4
3. Chest tube:	◉ No Answer ○ Right (1) ○ Left (2) ○ Bilateral (3) ○ None (4)	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)	◉ No Answer ○ Yes (1) ○ No (2)	sedate
2. Eye opening score:	◉ No Answer ○ Spontaneous (4) ○ To Voice (3) ○ To Pain (2) ○ None (1)	eye
3. Motor response score:	◉ No Answer ○ Obeys commands (6) ○ Localizes to Pain (5) ○ Flexor withdrawal (4) ○ Abnormal flexion (3) ○ Extension (2) ○ Flaccid (1)	motor
4. Verbal response score:	◉ No Answer ○ Oriented [or appears oriented, if on ventilator] (5) ○ Confused [or questionably oriented, if on ventilator] (4) ○ Inappropriate [or generally unresponsive, if on ventilator] (3) ○ Incomprehensible (2) ○ None (1)	verbal
5. Total GCS:	[ ]	gcst
IF PATIENT ON NEUROMUSCULAR BLOCKERS LAST 24 HOURS --> FORM COMPLETE.		
6. Does patient follow commands?	◉ No Answer ○ Yes (1) ○ No (2)	cmds
7. Neck flexor?	◉ No Answer ○ No contraction (1) ○ Trace contraction (2) ○ Active contraction against gravity (3) ○ Active movement against gravity and resistance (4) ○ Normal power (5)	nckflex
8. Neck extensor?	◉ No Answer ○ No contraction (1) ○ Trace contraction (2) ○ Active contraction against gravity (3) ○ Active movement against gravity and resistance (4) ○ Normal power (5)	nckext

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

METATRIAL

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

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table= medicati

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

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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?	⦿ No Answer ○ Yes (1) ○ No (2)	ventm1
1b. Pressure support?	⦿ No Answer ○ Yes (1) ○ No (2)	ventm2
1c. Assist/Control?	⦿ No Answer ○ Yes (1) ○ No (2)	ventm3
1d. Pressure control?	⦿ No Answer ○ Yes (1) ○ No (2)	ventm4
1e. PC IRV?	⦿ No Answer ○ Yes (1) ○ No (2)	ventm5
1f. Other:	[ ]	ventm6
2. Calculated delivered tidal volume:	[ ] ml	cdtv
3. Pressure control level (if on pressure control ventilation):	[ ] cm H2O	pcl
4. Pressure support level (if on pressure support ventilation):	[ ] cm H2O	psvp
5. Set rate:	[ ] breaths/min	srat
6. Total respiratory rate:	[ ] breaths/min	trespr
7. Total minute ventilation:	[ ] L/min	tmnvnt
8. PEEP:	[ ] cm H2O	peep
9. Plateau pressure (cm H2O, 0.5 sec end-inspiratory pause):	[ ] cm H2O	platp
10. FiO2:	[ ]	fio2vent
11. PaO2:	[ ] mm Hg	pao2vent
12. PaCO2:	[ ] mm Hg	paco2_vt
13. Arterial pH:	[ ]	artph
14. SpO2:	[ ] %	sats
15. Static Thoracic Compliance:	[ ] mL/cm H2O/kg IBW	stc
16. Patient position:	⦿ No Answer ○ Supine (1) ○ Prone (2) ○ Other (3)	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

METATRIAL

USE MOST RECENT VALUES IN THE 24 HOUR PERIOD PRIOR TO THE TIME OF RANDOMIZATION	
1. Heart rate:	[ ] beats/min	hrate
2. Systolic blood pressure:	[ ] mm Hg	sysbp
3. Diastolic blood pressure:	[ ] mm Hg	diasbp
4. Temperature:	[ ] C [ ] F	ctemp ftemp
5. Height:	[ ] cm [ ] in cheight	iheight
6. Gender:	⊙ No Answer ○ Male (1) ○ Female (2)	gender
7. Calculated Predicted Body Weight:	[ ] kg	pbw
8. Measured body weight:	[ ] kg [ ] lbs kweight	lweight
9. Hematocrit:	[ ] %	crit
10. White blood cell count:	[ ] cells/mm^3	wbcct
11. Glucose:	[ ] mg/dL	glucose
12. Amylase:	[ ] units/L	amylase
13. Albumin level:	[ ] g/dL	albumin
14a. Prothrombin time:	[ ] sec	prothr
14b. PT Control:	[ ] sec	ptcont

NOTE: height and weight outliers have been removed to deidentify data.

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.

1. Is the PaO2/FiO2 less than 80?	◉ No Answer ○ Yes (1) ○ No (2)	bpfr
2. Is ETT size < 7.0?	◉ No Answer ○ Yes (1) ○ No (2)	betts
3. Is there marked cardiovascular instablility? • 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?)	◉ No Answer ○ Yes (1) ○ No (2)	bcvin
4. Does patient have a known elevated ICP (sustained ICP greater than or equal to 20)?	◉ No Answer ○ Yes (1) ○ No (2)	beicp

IF QUESTIONS 1-4 NO, PATIENT IS ELIGIBLE FOR BRONCHOALVEOLAR LAVAGE. OBTAIN FLUID ANALYSIS OF BAL.

5. Cell count: • **EXAMPLE: 250,000 = 2.5 x 10 ^ 5 cells/mm^3**	[____] x 10 ^ [____] cells/mm^3	bcell1 scinote1
DIFFERENTIAL:		
6a. Alveolar macrophages:	[____]	bdiff1
6b. PMNS:	[____]	bdiff2
6c. Eosinophils:	[____]	bdiff3
6d. Lymphocytes:	[____]	bdiff4
6e. Other:	[____]	bdiff5
7. Quantitative culture 1 count (if available):	[____] x 10 ^ [____] colony forming units/mL lavage fluid	quant1 scinote2
	◉ No Answer ○ Staph aureus (1) ○ Staph epidermidis (2) ○ Strep pneumoniae (3) ○ Enterococcus (4) ○ Other Gram Positive Cocci (5) ○ Pseudomonas species (6)	

8. Organism 1:	○ Hemophilus influenza (7) ○ Other Gram Negative Rod (8) ○ B. cattarhalis (9) ○ Other Gram Negative Cocci (10) ○ Candida species (11) ○ Torulopsis species (12) ○ Aspergillus species (13) ○ Varicella zoster (14) ○ Herpes simplex (15) ○ CMV (16) ○ Other virus (17) ○ Pneumocystis carinii (18) ○ Mycobacterium tuberculosis (19) ○ Other Mycobacterium (20) ○ Other organism (21)	borgn1
9. Quantitative culture 2 count (if available):	[ ] x 10 ^ [ ] colony forming units/mL lavage fluid	quant4 scinote3
10. Organism 2:	◉ No Answer ○ Staph aureus (1) ○ Staph epidermidis (2) ○ Strep pneumoniae (3) ○ Enterococcus (4) ○ Other Gram Positive Cocci (5) ○ Pseudomonas species (6) ○ Hemophilus influenza (7) ○ Other Gram Negative Rod (8) ○ B. cattarhalis (9) ○ Other Gram Negative Cocci (10) ○ Candida species (11) ○ Torulopsis species (12) ○ Aspergillus species (13) ○ Varicella zoster (14) ○ Herpes simplex (15) ○ CMV (16) ○ Other virus (17) ○ Pneumocystis carinii (18) ○ Mycobacterium tuberculosis (19) ○ Other Mycobacterium (20) ○ Other organism (21)	borgn2
11. Quantitative culture 3 count (if available):	[ ] x !0 ^ [ ] colony forming units/mL lavage fluid	quant7 scinote4
	◉ No Answer ○ Staph aureus (1)	

12. Organism 3:	○ Staph epidermidis (2)
	○ Strep pneumoniae (3)
	○ Enterococcus (4)
	○ Other Gram Positive Cocci (5)
	○ Pseudomonas species (6)
	○ Hemophilus influenza (7)
	○ Other Gram Negative Rod (8)
	○ B. cattarhalis (9)
	○ Other Gram Negative Cocci (10)
	○ Candida species (11)
	○ Torulopsis species (12)
	○ Aspergillus species (13)
	○ Varicella zoster (14)
	○ Herpes simplex (15)
	○ CMV (16)
	○ Other virus (17)
	○ Pneumocystic carinii (18)
	○ Mycobacterium tuberculosis (19)
	○ Other Mycobacterium (20)
	○ Other organism (21)

borgn3

COLLECT BLOOD SAMPLE FOR STORAGE (CYTOKINES AND PROCOLLAGEN PEPTIDE III LEVEL); PROCESS BAL FOR STORAGE.

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
[_____] Date	[____]	[____]	[____]	[____]	[____]	[____]	⦿ No Answer ○ Yes (1) ○ No (2)
Data Entry Grid							

startdat   sysbpbru bruspafi   brusplat bruscrea brusbili   bruscpk vasobrus

On Study Glasgow Coma and Neuro Exam   **Visit Date:**   visit

table= glasgow

1. Is patient on a sedative or neuromuscular blocker? (If yes, use best GCS estimate):	⦿ No Answer ○ Yes (1) ○ No (2)

sedate

2. Eye opening score:	⦿ No Answer ○ Spontaneous (4) ○ To Voice (3) ○ To Pain (2) ○ None (1)

eye

3. Motor response score:	⦿ No Answer ○ Obeys commands (6) ○ Localizes to pain (5) ○ Flexor withdrawal (4) ○ Abnormal flexion (3) ○ Extension (2) ○ Flaccid (1)

motor

4. Verbal response score:	⦿ No Answer ○ Oriented [or appears oriented, if on ventilator] (5) ○ Confused [or questionably oriented, if on ventilator] (4) ○ Inappropriate [or generally unresponsive, if on ventilator] (3) ○ Incomprehensible (2) ○ None (1)

verbal

5. Total GCS:	[ ]

gcst

IF PATIENT ON NEUROMUSCULAR BLOCKERS LAST 24 HOURS --> FORM COMPLETE.

6. Does patient follow commands?	⦿ No Answer ○ Yes (1) ○ No (2)

cmds

7. Neck flexor?	⦿ No Answer ○ No contraction (1) ○ Trace contraction (2) ○ Active contraction against gravity (3) ○ Active movement against gravity and resistance (4) ○ Normal power (5)

nckflex

8. Neck extensor?	⦿ No Answer ○ No contraction (1) ○ Trace contraction (2) ○ Active contraction against gravity (3) ○ Active movement against gravity and resistance (4) ○ Normal power (5)

nckext

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

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.

METATRIAL

On Study Monitoring and Medications   **Visit Date:**   visit

table= medicati

1. Does chart review suggest new infection this calendar day? • 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.	⦿ No Answer ○ Yes (1) ○ No (2)	chart2
2. Do clinicians suspect new nosocomial pneumonia?	⦿ No Answer ○ Yes (1) ○ No (2)	newn2
INDICATE IF ANY OF THE FOLLOWING MEDICATIONS WERE ADMINISTERED DURING THIS CALENDAR DAY.		
3. Have sedatives or tranquilizers been administered?	⦿ No Answer ○ Yes (1) ○ No (2)	seds
4. Have neuromuscular blocking agents been administered?	⦿ No Answer ○ Yes (1) ○ No (2)	nmba
5. Have antifungal agents been administered?	⦿ No Answer ○ Yes (1) ○ No (2)	antif
6. Has amphotericin been administered?	⦿ No Answer ○ Yes (1) ○ No (2)	ampho
7a. Have aminoglycosides been administered? (if yes, specify below):	⦿ No Answer ○ Yes (1) ○ No (2)	amino
7b. Aminoglycosides administered (check all that apply):	☐ Gentamicin (1) ☐ Tobramycin (2) ☐ Amikacin (3) ☐ Other Aminoglycosides (4)	amino12 amino13 amino14 amino15
8a. Have cephalosporins been administered? (if yes, specify below):	⦿ No Answer ○ Yes (1) ○ No (2)	ceph
8b. Cephalosporins administered (check all that apply):	☐ Cefazolin (1) ☐ Cefotaxime (2) ☐ Cefotetan (3) ☐ Ceftazidime (4) ☐ Ceftriaxone (5) ☐ Cefuroxime (6) ☐ Cefepime (7) ☐ Other Cephalosporins (8)	ceph12 ceph13 ceph14 ceph15 ceph16 ceph17 ceph18 ceph19
9a. Have macrolides been administered? (if yes, specify below):	⦿ No Answer ○ Yes (1) ○ No (2)	mac
	☐ Azithromycin (1)	mac12

29

9b. Macrolides administered (check all that apply):	☐ Clarithromycin (2) ☐ Clindamycin (3) ☐ Erythromycin (4)	mac13 mac14 mac15
10a. Have penicillins been administered? (if yes, specify below):	◉ No Answer ○ Yes (1) ○ No (2)	pcn
10b. Penicillins administered (check all that apply):	☐ Ampicillin (1) ☐ Ampicillin-Subactam (2) ☐ Aztreonam (3) ☐ Imipenam-Cilistatin (4) ☐ Nafcillin (5) ☐ Penicillin (6) ☐ Piperacillin (7) ☐ Ticarcillin (8) ☐ Other Penicillins (9)	pcn12 pcn13 pcn14 pcn15 pcn16 pcn17 pcn18 pcn19 pcn20
11a. Have quinolones been administered? (if yes, specify below):	◉ No Answer ○ Yes (1) ○ No (2)	quino
11b. Quinolones administered (check all that apply):	☐ Ciprofloxacin (1) ☐ Ofloxacin (2) ☐ Other Quinolones (3)	quino12 quino13 quino14
12. Vancomycin administered?	◉ No Answer ○ Yes (1) ○ No (2)	vanco
13. Other antibiotics administered?	◉ No Answer ○ Yes (1) ○ No (2)	oant
14. Antipsychotics administered?	◉ No Answer ○ Yes (1) ○ No (2)	apsych
15. Antivirals administered?	◉ No Answer ○ Yes (1) ○ No (2)	avrls
16a. Experimental therapies employed? (If yes, specify below):	◉ No Answer ○ Yes (1) ○ No (2)	expt1
16b. If yes, select experimental therapies:	☐ Nitric Oxide (1) ☐ Surfactant therapy (2) ☐ Partial liquid ventilation (3) ☐ ECMO (4) ☐ IVOX (5) ☐ HFV or HFO (6) ☐ Prone positioning (7) ☐ Inhaled PGI or PGE (8) ☐ Intravenous PGI or PGE (9) ☐ 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?	⦿ No Answer ○ Yes (1) ○ No (2)	ventm1
1b. Pressure support?	⦿ No Answer ○ Yes (1) ○ No (2)	ventm2
1c. Assist/Control?	⦿ No Answer ○ Yes (1) ○ No (2)	ventm3
1d. Pressure control?	⦿ No Answer ○ Yes (1) ○ No (2)	ventm4
1e. PC IRV?	⦿ No Answer ○ Yes (1) ○ No (2)	ventm5
1f. Other:	[ ]	ventm6
2. Calculated delivered tidal volume (if on volume cycled mode):	[ ] ml	cdtv
3. Pressure control level (if on pressure control ventilation):	[ ] cm H2O	pcl
4. Pressure support level (if on pressure support ventilation):	[ ] cm H2O	psvp
5. Set rate:	[ ] breaths/min	srat
6. Total respiratory rate:	[ ] breaths/min	trespr
7. Total minute ventilation:	[ ] L/min	tmnvnt
8. PEEP:	[ ] cm H2O	peep
9. Plateau pressure (cm H2O, 0.5 sec end-inspiratory pause):	[ ] cm H2O	platp
10. FiO2:	[ ]	fio2vent
11. PaO2 on current FiO2:	[ ] mm Hg	pao2vent
12. PaCO2 on current ventilator settings:	[ ] mm Hg	paco2_vt
13. Arterial pH:	[ ]	artph
14. SpO2 on current FiO2:	[ ] %	sats
15. Static Thoracic Compliance:	[ ] mL/cm H2O/kg IBW	stc
16. Patient position:	⦿ No Answer ○ Supine (1) ○ Prone (2) ○ Other (3)	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: [ ] beats/min	hrate
2. Systolic blood pressure: [ ] mm Hg	sysbp
3. Diastolic blood pressure: [ ] mm Hg	diasbp
4. Temperature: [ ] C [ ] F	ctemp ftemp
ENTER LAB VALUES, IF AVAILABLE, FOR DAYS 7, 14, 21, AND 28.	
5. Hematocrit: [ ] %	crit
6. White blood cell count: [ ] cells/mm^3	wbcct
7. Glucose: [ ] mg/dL	glucose
8. Amylase level: [ ] units/L	amylase
NOTE: DRAW BLOOD FOR STORAGE ON DAY 7.	

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

METATRIAL

ATTACH COMMENT EXPLAINING REASON IF ANY BLOOD OR BAL SAMPLES WERE NOT COLLECTED.		
Day 0		
1a. Was blood drawn for storage on day 0?	○ No Answer ○ Yes (1) ○ No (2)	bcyt
1b. If yes, give date blood taken for storage:	[　　　　] Date	bcytdate
2a. Was BAL taken for storage on day 0?	○ No Answer ○ Yes (1) ○ No (2)	balp
2b. If yes, give date of BAL collection for storage:	[　　　　] Date	baldate
Day 7		
3a. Was blood drawn for storage on day 7?	○ No Answer ○ Yes (1) ○ No (2)	bcyt1
3b. Date blood taken for storage (date of day 7):	[　　　　] Date	bcytdat1
4a. Was BAL taken for storage on day 7?	○ No Answer ○ Yes (1) ○ No (2)	balp1
4b. If yes, give date BAL taken for storage (date of day 7):	[　　　　] Date	baldate2

DURING THIS CALENDAR DAY	
1. Was the patient permanently withdrawn from LaSRS?	◉ No Answer ○ Yes (1) ○ No (2)

wdrawn

2a. Was study drug administered?	◉ No Answer ○ Yes (1) ○ No (2)

drugadmn

2b. Total dose of study drug administered this calendar day:	[_____] mg

drugdose

3. Is study drug being tapered?	◉ No Answer ○ No (1) ○ Slow (2) ○ Rapid (3)

taper

4. At 0600, patient on:	◉ No Answer ○ Volume Assist/Control Ventilation (1) ○ Pressure Support Ventilation (2) ○ Unassisted Breathing (3) ○ Other -- specify below (4)

NOTE: some wean4 entries have been modified to deidentify data

wean1

4a. Other:	[_____]

wean2

5. Did patient meet weaning evaluation criteria?	◉ No Answer ○ Yes (1) ○ No (2) ○ Not tried/Evaluated (3)

weancrit

5a. If 5 is yes, did patient pass 5 minute CPAP trial?	◉ No Answer ○ Yes (1) ○ No (2)

cpaptrl

6. Were there any attempts to wean PS by 5 cm H2O?	◉ No Answer ○ Yes (1) ○ No -- specify reason below (2)

wean3

6i. If no, why not?	[_____]

wean4

WEANING HISTORY: Record initial and subsequent pressure support levels along with their corresponding starting times each time the pressure support level is changed.

	Pressure Support Level (cm H2O)	Time (hh:mm)		Pressure Support Level (cm H2O)	Time (hh:mm)
6a.	weanhx1	weanhx2	6b.	weanhx3	weanhx4
6c.	weanhx5	weanhx6	6d.	weanhx7	weanhx8
6e.	weanhx9	weanhx10	6f.	weanhx11	weanhx12
6g.	weanhx13	weanhx14	6h.	weanhx15	weanhx16

7. Did patient tolerate a trial of spontaneous breathing for more than two hours?	◉ No Answer ○ Yes (1) ○ No (2) ○ Not tried/Evaluated (3)

wean5

8. Did patient complete 48 hours of unassisted breathing on this calendar day?	◉ No Answer ○ Yes (1) ○ No (2)

wean6

Deep Tissue Abscess　　table=　abscess　　　　　　**Visit Date:**　visit

THIS FORM IS TO BE COMPLETED FOR ABDOMINAL OR OTHER DEEP TISSUE ABSCESSES	
1. Date of diagnosis of abscess:	[＿＿＿＿＿] [Date]

dtisu1

2. Organism:	◉ No Answer
	◯ Staph aureus (1)
	◯ Staph epidermidis (2)
	◯ Strep pneumoniae (3)
	◯ Enterococcus (4)
	◯ Other Gram Positive Coccus (5)
	◯ Pseudomonas species (6)
	◯ Hemophilus influenza (7)
	◯ Other Gram Negative Rod (8)
	◯ B. cattarhalis (9)
	◯ Other Gram Negative Cocci (10)
	◯ Candida species (11)
	◯ Torulopsis species (12)
	◯ Aspergillus species (13)
	◯ Varicella zoster (14)
	◯ Herpes simplex (15)
	◯ CMV (16)
	◯ Other virus (17)
	◯ None identified/obtained (18)
	◯ Other organism (19)

dtisu2

3. Site of infection/abscess:	◉ No Answer
	◯ Hepatic abscess (1)
	◯ Splenic abscess (2)
	◯ Pericolic abscess (3)
	◯ Pancreatic abscess (4)
	◯ Cholecystitis (5)
	◯ Myositis (6)
	◯ Other (7)

dtisu3

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.

Bacteremia   table= bacter   **Visit Date:**   visit

Date of blood culture	Time of blood draw	Organism recovered
[ ] Date startdat	[ ] hh:mm btime1	⦿ No Answer ○ Staph aureus (1) ○ Staph epidermidis (2) ○ Strep pneumoniae (3) ○ Enterococcus (4) ○ Other Gram Positive Cocci (5) ○ Pseudomonas species (6) ○ Hemophilus influenza (7) ○ Other Gram Negative Rod (8) ○ B. cattarhalis (9) ○ Other Gram Negative Cocci (10) ○ Candida species (11) ○ Torulopsis species (12) ○ Aspergillus species (13) ○ Varicella zoster (14) ○ Herpes simplex (15) ○ CMV (16) ○ Other virus (17) ○ Other organism (18)

                                                            bacorg1

Empyema   table= empyema   **Visit Date:**   visit

METATRIAL

1. Date of diagnosis of empyema:	[ ] [Date]

empye1

2. Organism:	◉ No Answer
	○ Staph aureus (1)
	○ Staph epidermidis (2)
	○ Strep pneumoniae (3)
	○ Enterococcus (4)
	○ Other Gram Positive Coccus (5)
	○ Pseudomonas species (6)
	○ Hemophilus influenza (7)
	○ Other Gram Negative Rod (8)
	○ B. cattarhalis (9)
	○ Other Gram Negative Cocci (10)
	○ Candida species (11)
	○ Torulopsis species (12)
	○ Aspergillus species (13)
	○ Varicella zoster (14)
	○ Herpes simplex (15)
	○ CMV (16)
	○ Other virus (17)
	○ None identified/obtained (18)
	○ Other organism (19)

empye2

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.

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Fungal Infection   table= fungal   **Visit Date:**   visit

1a. Is blood culture positive for yeast infection? (If yes, give date below):	⊙ No Answer ○ Yes (1) ○ No (2)	fungl1
1b. Date of positive culture:	[_____] [Date]	fungl2
2a. Is there evidence of deep tissue infection? (endophthalmitis, hepatic/splenic abscesses, etc.); If yes, give date below:	⊙ No Answer ○ Yes (1) ○ No (2)	fungl3
2b. Date of diagnosis of infection:	[_____] [Date]	fungl4
3a. Does patient have unexplained fever with 3 sites of colonization? (If yes, give date below):	⊙ No Answer ○ Yes (1) ○ No (2)	fungl5
3b. Date of diagnosis:	[_____] [Date]	fungl6
4a. Does patient have oral or mucosal candidiasis? (If yes, give date below):	⊙ No Answer ○ Yes (1) ○ No (2)	fungl7
4b. Date of diagnosis of candidiasis:	[_____] [Date]	fungl8
5. Fungal infection causative organism:	⊙ No Answer ○ Candida species (1) ○ Torulopsis species (2) ○ Aspergillus species (3) ○ 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:	[_____] [Date]	mengt1
2. Organism recovered from CSF:	⦿ No Answer ○ Neiseria meningiditis (1) ○ Strep pneumoniae (2) ○ Hemophilus influenza (3) ○ Other Gram Negative Rod (4) ○ Staph aureus (5) ○ Other organism (6)	mengt2
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.		

Peritonitis table= periton   **Visit Date:** visit

THIS FORM IS TO BE COMPLETED FOR PERITONITIS *NOT* 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.	
1. Date of diagnosis of peritonitis:	[_____] [Date]

pertn1

2. Peritoneal fluid culture:	◉ No Answer ○ Staph aureus (1) ○ Staph epidermidis (2) ○ Strep pneumoniae (3) ○ Enterococcus (4) ○ Other Gram Positive Coccus (5) ○ Pseudomonas species (6) ○ Hemophilus influenza (7) ○ Other Gram Negative Rod (8) ○ B. cattarhalis (9) ○ Other Gram Negative Cocci (10) ○ Candida species (11) ○ Torulopsis species (12) ○ Aspergillus species (13) ○ Varicella zoster (14) ○ Herpes simplex (15) ○ CMV (16) ○ Other virus (17) ○ None identified/obtained (18) ○ Other (19)

pertn2

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.

METATRIAL

1. Date of pneumonia diagnosis:	[_____] [Date]	pneum1

2. WITHIN A 48 HOUR PERIOD, DID THE PATIENT HAVE:

2a. Chest radiograph showing new infiltrate that has persisted for 48 hours?	⦿ No Answer ○ Yes (1) ○ No (2)	pneum9
2b. New fever, hypothermia, leukocytosis, or leukopenia?	⦿ No Answer ○ Yes (1) ○ No (2)	pneum2
3. Was an endotracheal aspirate sent for gram stain?	⦿ No Answer ○ Yes (1) ○ No (2)	pneum3
4. Was an endotracheal aspirate sent for culture?	⦿ No Answer ○ Yes (1) ○ No (2)	pneum4
5a. Was there bacteriological confirmation of episode of suspected pneumonia?	⦿ No Answer ○ Yes (1) ○ No (2)	pneum5
5b. Organism 1:	⦿ No Answer ○ Staph aureus (1) ○ Staph epidermidis (2) ○ Strep pneumoniae (3) ○ Enterococcus (4) ○ Other Gram Positive Coccus (5) ○ Pseudomonas species (6) ○ Hemophilus influenza (7) ○ Other Gram Negative Rod (8) ○ B. cattarhalis (9) ○ Other Gram Negative Cocci (10) ○ Candida species (11) ○ Torulopsis species (12) ○ Aspergillus species (13) ○ Varicella zoster (14) ○ Herpes simplex (15) ○ CMV (16) ○ Other virus (17) ○ Mycobacterium tuberculosis (18) ○ Other Mycobacterium (19) ○ Pneumocystic carinii (20) ○ Other organism (21)	pneum6
	⦿ No Answer ○ Staph aureus (1) ○ Staph epidermidis (2) ○ Strep pneumoniae (3)	

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5c. Organism 2 (if more than one present):	◯ Enterococcus (4) ◯ Other Gram Positive Coccus (5) ◯ Pseudomonas species (6) ◯ Hemophilus influenza (7) ◯ Other Gram Negative Rod (8) ◯ B. cattarhalis (9) ◯ Other Gram Negative Cocci (10) ◯ Candida species (11) ◯ Torulopsis species (12) ◯ Aspergillus species (13) ◯ Varicella zoster (14) ◯ Herpes simplex (15) ◯ CMV (16) ◯ Other virus (17) ◯ Mycobacterium tuberculosis (18) ◯ Other Mycobacterium (19) ◯ Pneumocystis carinii (20) ◯ Other organism (21)	pneum7
5d. Organism 3 (if more than two present):	◉ No Answer ◯ Staph aureus (1) ◯ Staph epidermidis (2) ◯ Strep pneumoniae (3) ◯ Enterococcus (4) ◯ Other Gram Positive Coccus (5) ◯ Pseudomonas species (6) ◯ Hemophilus influenza (7) ◯ Other Gram Negative Rod (8) ◯ B. cattarhalis (9) ◯ Other Gram Negative Cocci (10) ◯ Candida species (11) ◯ Torulopsis species (12) ◯ Aspergillus species (13) ◯ Varicella zoster (14) ◯ Herpes simplex (15) ◯ CMV (16) ◯ Other virus (17) ◯ Mycobacterium tuberculosis (18) ◯ Other Mycobacterium (19) ◯ Pneumocystis carinii (20) ◯ Other organism (21)	pneum8

IF SEPTIC SHOCK DEVELOPED AS A CONSEQUENCE OF THIS INFECTION, FILL OUT SEPTIC SHOCK FORM (IF NOT ALREADY DONE).

FILL OUT THIS FORM FOR EACH EPISODE OF SEPTIC SHOCK.	
1a. Were two or more of the following SIRS criteria present? • Temperature > 38 C or < 36 C *OR* • Heart rate > 90 beats/min *OR* • Respiratory rate > 20 breaths/min or PaCO2 < 32 mm Hg (if on unassisted breathing) *OR* • WBC > 12,000 or < 4,000 or > 10% immature (bands)	⦿ No Answer ○ Yes (1) ○ No (2)	septic1
1b. If yes, give date of SIRS onset:	[ ] [Date]	septic2
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.		
2a. Systolic BP less than 90 mm Hg?	⦿ No Answer ○ Yes (1) ○ No (2)	septic3
2b. BP reduction greater than or equal to 40 mm Hg from baseline?	⦿ No Answer ○ Yes (1) ○ No (2)	septic4
2c. Pressor requirement to maintain BP?	⦿ No Answer ○ Yes (1) ○ No (2)	septic5
2d. Date first shock criteria met:	[ ] [Date]	septic6
3. Was the primary site of infection identified? (If yes, give site below):	⦿ No Answer ○ Yes (1) ○ No (2)	septic7
3a. Primary site of infection:	⦿ No Answer ○ Pneumonia (1) ○ Peritonitis (2) ○ Wound infection (3) ○ Meningitis (4) ○ Empyema (5) ○ Biliary tract (6) ○ Abdominal abscess (7) ○ C. difficile colitis (8) ○ Urinary tract (9) ○ Vascular line (10) ○ Peritonitis on dialysis (11) ○ Sinusitis (12) ○ Skin infection (13)	septic8

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	○ Septic arthritis (14) ○ Other (15)	
4a. Did the shock episode resolve? (If yes, give date below):	● No Answer ○ Yes (1) ○ No (2)	septic9
4b. Date of shock resolution:	[ ] [Date]	septic10

Viral Infection   table= viral   **Visit Date:**   visit

METATRIAL

THIS FORM IS TO BE COMPLETED FOR DISSEMINATED VIRAL INFECTIONS.	
1. Date of diagnosis of viral infection:	☐ [Date]
2a. Causative organism 1:	◉ No Answer ○ Herpes simplex (1) ○ Varicella zoster (2) ○ CMV (3) ○ Other (4)
2b. Causative organism 2 (if more than one virus present):	◉ No Answer ○ Herpes simplex (1) ○ Varicella zoster (2) ○ CMV (3) ○ 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:	[ ] [Date]

wound1

wound2

2. Wound culture causative organism:

- ⊙ No Answer
- ○ Staph aureus (1)
- ○ Staph epidermidis (2)
- ○ Strep pneumoniae (3)
- ○ Enterococcus (4)
- ○ Other Gram Positive Coccus (5)
- ○ Pseudomonas species (6)
- ○ Hemophilus influenza (7)
- ○ Other Gram Negative Rod (8)
- ○ B. cattarhalis (9)
- ○ Other Gram Negative Cocci (10)
- ○ Candida species (11)
- ○ Torulopsis species (12)
- ○ Aspergillus species (13)
- ○ Varicella zoster (14)
- ○ Herpes simplex (15)
- ○ CMV (16)
- ○ Other virus (17)
- ○ None identified/obtained (18)
- ○ 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.

Other Infection   table= oth_inf   **Visit Date:**   visit

1a. C. difficile colitis? (If yes, give date below):	⦿ No Answer ○ Yes (1) ○ No (2)	othrin1
1b. Date of C. difficile colitis diagnosis:	[ ] Date	othrin2
2a. Indwelling vascular line infection? (If yes, give date below):	⦿ No Answer ○ Yes (1) ○ No (2)	othrin3
2b. Date of vascular line infection diagnosis:	[ ] Date	othrin4
3a. Peritonitis (on peritoneal dialysis)? (If yes, give date below):	⦿ No Answer ○ Yes (1) ○ No (2)	othrin5
3b. Date of peritonitis diagnosis:	[ ] Date	othrin6
4a. Sinus infection? (If yes, give date below):	⦿ No Answer ○ Yes (1) ○ No (2)	othrin7
4b. Date of sinus infection diagnosis:	[ ] Date	othrin8
5a. Skin infection? (If yes, give date below):	⦿ No Answer ○ Yes (1) ○ No (2)	othrin9
5b. Date of skin infection diagnosis:	[ ] Date	othrin10
6a. Septic arthritis? (If yes, give date below):	⦿ No Answer ○ Yes (1) ○ No (2)	othrin11
6b. Date of septic arthritis diagnosis:	[ ] Date	othrin12
7a. Urinary tract infection? (If yes, give date below):	⦿ No Answer ○ Yes (1) ○ No (2)	othrin13
7b. Date of UTI diagnosis:	[ ] Date	othrin14
8a. Other infection? (If yes, give date below):	⦿ No Answer ○ Yes (1) ○ No (2)	othrin15
8b. Date of diagnosis of other infection:	[ ] 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?	◉ No Answer ○ Yes (1) ○ No (2)	chart1
1b. Myositis?	◉ No Answer ○ Yes (1) ○ No (2)	chart3
1c. Neuropathy?	◉ No Answer ○ Yes (1) ○ No (2)	chart4
1d. Muscle weakness?	◉ No Answer ○ Yes (1) ○ No (2)	chart5
1e. Paralysis?	◉ No Answer ○ Yes (1) ○ No (2)	chart6

2. If there is evidence of conditions A-E above, specify distribution (mark all that apply)

2a. Upper extremity	☐	locate1
2b. Lower extremity	☐	locate2
2c. Neck	☐	locate3
2d. Unknown	☐	locate4
3. Date of onset of clinical abnormality (if known):	[_____] Date	dtonset
4. Duration of clinical abnormality in days (if known):	[_____]	duratabn
5. Evidence of sensory deficit?	◉ No Answer ○ Yes (1) ○ No (2) ○ Unknown (3)	sensdef

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Study Termination   table= study_te   **Visit Date:**   visit

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).** **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.**	

Visit date (date of termination from study):	[_____] [Date]	visit
1. Patient status:	◉ No Answer ○ Home with unassisted breathing (1) ○ Dead prior to discharge home with unassisted breathing or dead before UAB at home for 48 hrs. (2) ○ Other (3)	status
1a. If 1, give date patient was discharged home on unassisted breathing:	[_____] [Date]	st1dt
1b. If 2, give date of death:	[_____] [Date]	st2dt
1c. If 3, give date of last patient contact:	[_____] [Date]	st3dt
2. Was patient able to sustain continuous unassisted breathing for at least 48 hrs during first 28 days?	◉ No Answer ○ Yes (1) ○ No (2)	sust28
2a. If yes, give calendar date of first period of unassisted breathing lasting greater than or equal to 48 hours:	[_____] [Date]	unassist
3. Did patient return to assisted breathing during the first 28 days after achieving unassisted breathing?	◉ No Answer ○ Yes (1) ○ No (2)	assist
3a. If yes, give number of calendar days on which the patient required assisted breathing between date in 2a and day 28:	[_____]	asdays
4. Was patient discharged alive from ICU during first 28 days of enrollment?	◉ No Answer ○ Yes (1) ○ No (2)	icu
4a. If yes, give date of discharge from ICU:	[_____] [Date]	tm_icudt
5. Did patient return to ICU during		

first 28 days of enrollment?	⊙ No Answer ○ Yes (1) ○ 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:	[ ]	ricudays
6. Was the patient discharged alive from the study hospital?	⊙ No Answer ○ Yes (1) ○ No (2)	alive
6a. If yes, give date of study hospital discharge:	[ ] [Date]	alivedt