TABLE OF CONTENTS

NIH ARDS NETWORK

Lisofylline and Respiratory Management in Acute Lung Injury/Acute Respiratory Distress Syndrome (ARDSnet Study 01 and 03)

CASE REPORT FORM INSTRUCTIONS
Version I

January 8, 1998

This manual contains instructions for completing the case report forms (CRF) on patients enrolled in the ARDSnet Studies: 01 and 03 and replaces Version 2 of the CRF Instructions Dated October 24, 1996.

The format of the instructions is similar to the format of the case report form. Each section of the instructions has a title at the top of the first page similar to the title of the corresponding case report form pages. Within each section, the sequence of instructions is identical to the sequence of the questions on the case report form pages.

Some of the case report form pages must be completed only once on each patient (e.g., "ENROLLMENT CRITERIA" and "BASELINE VENTILATOR PARAMETERS"). Other case report form pages must be completed on several dates after enrollment (e.g., "ON STUDY VITAL SIGNS" AND "WEANING/VENTILATOR MONITORING FORM"). For these pages, the corresponding instruction manual pages for the specific date should be used.

Most of the questions on the case report form screens are self-explanatory, and the corresponding instructions are brief. For other questions, additional information is provided in the instructions or a reference to a specific protocol section or operating procedure is given.

Reminder about the use of the dot (.) missing value. The missing value can be entered into any field, but the coordinator should only use it to indicate that **the data will never be available**. For some of the questions, a value will not be available when the case report forms are being completed. This may occur because a value is pending or the chart was unavailable. In these instances, the coordinator should leave the field blank until the data can be obtained.

Additional Comments Form: This form is to be used in instances where further detail is needed that cannot be entered into the CRF fields. Enter the date, study day, and the corresponding form to which the comment applies and give a brief narrative in the space provided. Its main purpose is for documentation and/or verification of data entered on the CRF form. Information entered on an additional comment form cannot be accessed when generating the monthly reports.

ALI SCREENING FORM

This form should be completed on all patients meeting the study inclusion criteria in regularly screened ICUs. It should also be completed for patients meeting the inclusion criteria identified in other ICUs. A patient should not be screened and considered for enrollment more than once per hospitalization.

Inclusion Criteria

Acute onset of:

1. **$PaO_2/FiO_2 \leq 300$. If altitude > 1000m, use $(PaO_2/FiO_2) \leq (300) * (B.P./760)$**
2. **Bilateral infiltrates consistent with pulmonary edema on frontal chest radiograph. The infiltrates may be patchy, diffuse, homogenous, or asymmetric.**
3. **Requirement for positive pressure ventilation via endotracheal tube.**
4. **No evidence of left atrial hypertension (if measured, pulmonary arterial wedge pressure < 18 mmHg).**

If a patient meets all inclusion criteria and no exclusion criteria AND it has been < 36 hours since all inclusion criteria were first met, she/he is eligible for study enrollment.

ITEM	DEFINITION	DATA RULES
1. Acute Onset	Enter "1" (Yes) or "2" (No). Acute onset is defined as follows: PaO_2/FiO_2 ratio $\leq$ 300 (corrected for altitude) and bilateral infiltrates must be present for < 28 days. If either is present continuously for > 28 days, the condition is not considered "acute", and the patient is not eligible for enrollment.	Required field. "." not acceptable.
	THE FOLLOWING INCLUSION CRITERIA (2a-c,3) MUST OCCUR WITHIN A SINGLE 24 HOUR INTERVAL (ARDSnet Study 01, SECTION 4.2).	
2a. $PaO_2/FiO_2 \leq 300$ (corrected for altitude)	Example PaO_2/FiO_2 calculation: If PaO_2=89 and FiO_2=.50, then PaO_2/FiO_2=89/.50 = 178.	Required field. "." not acceptable.
2b. Bilateral infiltrates consistent with pulmonary edema	The infiltrates may be patchy, diffuse, homogeneous, or asymmetric. Infiltrates must not be caused solely by atelectasis, effusions, mass, plump or indistinct vessels, or shadows known to be chronic.	Required field. "." not acceptable.
2c. Receiving positive pressure ventilation via endotracheal tube	"Positive pressure ventilation" is defined as ventilation assistance wherein airway pressure is raised during inspiration and lowered during expiration. This excludes CPAP but includes Pressure Support, Pressure Control, and Assist/Control modes. "Endotracheal tube" may be an orotracheal, nasotracheal, or tracheostomy tube.	Required field. "." not acceptable.

ALI SCREENING FORM
(Continuation)

3. No clinical evidence of left atrial hypertension. If measured, pulmonary arterial wedge pressure $\leq$ 18 mmHg.	Enter "1" if there is **NO** evidence of left atrial hypertension; enter "2" if there **IS** evidence of left atrial hypertension.	Required field. "." not acceptable.
4. PaO_2	Enter the PaO_2 used to calculate the P/F ratio in 2a above	Required field. "." not acceptable.
5. FiO_2	Enter the FiO_2 used to calculate the P/F ratio in 2a above. Enter as a decimal (e.g., 50% should be entered as .50).	Required field. "." not acceptable.
6. Enter the date that all these criteria exist simultaneously	Enter the first calendar date when ALL inclusion criteria (2a-c, 3) first occur together. Example: If the P/F criterion was first met on 1/30/96 but the chest x-ray did not show bilateral infiltrates until 0600 on 2/1/96 and the patient STILL met the P/F criterion on 2/1/96, then the first date both were met would be 2/1/96.	Required field. "." not acceptable.
7. Patient Hospital ID #	Enter the unique number used by the hospital to identify the patient for medical record purposes.	Required field. "." not acceptable.
8. Gender	Enter "1" if the patient is male, "2" if the patient is female.	Required field. "." not acceptable (required to calculate IBW).
9. Ethnicity	1=White, not of Hispanic Origin, 2=Black, not of Hispanic Origin, 3=Hispanic, 4=Asian/Pacific Islander, 5=American Indian/Alaskan Native, 6=Other.	Required field. "." not acceptable.
10. Age	Enter patient's age in years at last birthday.	Required field. "." not acceptable.
11. Location	Enter number code to indicate patient's current location: MICU, SICU, Cardiac SICU, CCU, NeuroICU, Burn, Trauma, Cancer Unit, MICU/SICU, Other.	Required field. "." not acceptable.
12. Regularly Screened ICU	Enter "1" (Yes) if this ICU is screened at least 5 days each week.	Required field. "." not acceptable.
13a. Primary Reason for Exclusion	Enter the number from the list that indicates the most important condition that led to exclusion (if any). Refer to ARDSnet Study 01 section 4.3, Appendix A, and ARDSnet Study 03 section 5.2 for definitions of specified exclusion criteria such as chronic lung disease, terminal illness, chronic liver disease, morbid obesity, allergy to methylxanthines .	Required field. "." not acceptable.
13 b. Comment	If not excluded but not eligible at the time of study entry, complete this section.	Required field if 13a = not excluded.

ALI SCREENING FORM
(Continuation)

14. Lung Injury Category	Enter one primary and 0-4 secondary causes of lung injury: Trauma, Aspiration, Pneumonia, Sepsis, Multiple Transfusions, Other. The "primary" category should be the most immediate cause. E.g., a patient with multiple trauma who develops sepsis and then ALI: primary category = sepsis; secondary category = trauma.	Required field. "." not acceptable
QUESTIONS 15-17	If CCTG has indicated it will collect this information, then it is a required field. COMPLETE THESE FIELDS ONLY FOR SCREENED PATIENTS-NOT FOR ENROLLED PATIENTS.	
15. Date of unassisted breathing if unassisted breathing sustained for greater than 48 hours.	Enter the date that unassisted breathing began (first episode) if it continued for ≥ 48 hours.	Required field for SCREENED patients..
16. Date of Hospital Discharge	Enter the date patient was discharged from Study Hospital (alive or dead).	Required field for all CCTGs for patients who are SCREENED but not enrolled in study. "." is not acceptable.
17. Status at Hospital Discharge	Indicate whether patient was alive or dead at discharge from Study Hospital.	Required field for all CCTGs for patients who are SCREENED but not enrolled in study. "." is not acceptable.

INCLUSION CRITERIA
Enrollment

Complete this form on all patients who are being enrolled in the study.

ITEM	DEFINITION	DATA RULES
1. Acute Onset	Enter "1" (Yes) if both the PaO_2/FiO_2 and chest radiograph inclusion criteria (items 2a and 2b below) are of $\leq$ 28 days continuous duration.	Required field. "." not acceptable.
2. $PaO_2/FiO_2 \leq 300$, bilateral infiltrates ..., receiving positive pressure ventilation....	Enter "1" (Yes) if the ratio $PaO_2/FiO_2 \leq$ 300 (corrected for altitude) **AND** there are bilateral infiltrates consistent with pulmonary edema on chest radiograph (qualifying x-rays must be interpreted by the Center Principal Investigator or designee) **AND** if the patient is receiving positive pressure ventilation via endotracheal tube. "Positive pressure ventilation" is defined as ventilation assistance wherein airway pressure is raised during inspiration and lowered during expiration. This excludes CPAP alone but includes Pressure Support, Pressure Control, and Assist/Control modes. "Endotracheal tube" may be an orotracheal-, nasotracheal-, or tracheostomy tube.	Required field. "." not acceptable.
3. No clinical evidence of left atrial hypertension (if measured, pulmonary arterial wedge pressure $\leq$ 18 mmHg.	Enter "1" (Yes) if there is **NO** clinical evidence of left atrial hypertension (if measured, pulmonary arterial wedge pressure $\leq$ 18 mmHg). Enter "2" (No) if there **IS** evidence of left atrial hypertension (if measured, pulmonary arterial wedge pressure > 18 mmHg). If the PAWP is >18, it must fall to <18 and remain < 18 for 12 consecutive hours.	Required field. "." not acceptable.

EXCLUSION CRITERIA
Enrollment

Complete this form on all patients who are being enrolled in the study.

ITEM	DEFINITION	DATA RULES
1. Attending physician unwilling to participate?	Enter "1" (Yes) or "2" (No).	Required field. '.' not allowed.
2. Patient unwilling to participate?	Enter "1" (Yes) or "2" (No) if the patient or the patient's family are unwilling to participate in the trial.	Required field. '.' not allowed.
3. Unable to obtain informed consent?	Enter "1" (Yes) or "2" (No) if the investigators were unable to obtain informed consent. For example: if a patient was declared incompetent and investigators were unable to locate surrogates.	Required field. '.' not allowed.
4. Is patient < 18 years old?	Enter "1" (Yes) or "2" (No).	Required field. '.' not allowed.
5. Has patient participated in other intervention trials in ALI, ARDS or Sepsis within the past 30 days?	Enter "1" (Yes) or "2" (No).	Required field. '.' not allowed.
6. Has it been > 36 hours since all the inclusion criteria were met?	A patient must be enrolled, randomized, and initial ventilator changes made and first dose of study drug given within 36 hours of when all the inclusion criteria were first met. Enter "1" if the answer to the question is "Yes"; enter "2" if the answer is "No".	Required field. '.' not allowed.
7. Does the patient have neuromuscular disease that impairs the ability to ventilate spontaneously?	Enter "1" (Yes) or "2" (No). Ability to ventilate may be impaired by C_5 or higher spinal cord injury, amyotrophic lateral sclerosis, Guillain-Barre syndrome, myasthenia gravis, or other neuromuscular disease.	Required field. '.' not allowed.
8. Is patient pregnant?	Enter "1" (Yes) or "2" (No). If patient is female of reproductive age, obtain appropriate laboratory test for pregnancy (e.g. urine HCG).	Required field. '.' not allowed.
9. Does the patient have elevated intracranial pressure, tricyclic antidepressant overdose, HgbSS, HgbSC, or other conditions where hypercapnia would be contraindicated?	Enter "1" (Yes) or "2" (No). Refer to Protocol Appendix A for definitions of elevated intracranial pressure. If tricyclic overdose and level not elevated, enter "2"; if no level available or level elevated, enter "1".	Required field. '.' not allowed.

EXCLUSION CRITIERIA
(Continuation)

10. Does patient have severe chronic respiratory disease?	Enter "1" (Yes) or "2" (No). Severe chronic respiratory disease is defined in ARDSnet Study 01, Appendix A.	Required field. "." not allowed.
11. Does patient have burns greater than or equal to 30% total body surface area?	Enter "1" (Yes) or "2" (No).	Required field. "." not allowed.
12. Does patient have a malignancy or other chronic irreversible disease or condition for which 6 month mortality is estimated at greater than 50%.	Enter "1" (Yes) or "2" (No).	Required field. "." not allowed.
13. Has the patient had either a bone marrow transplant or lung transplant.	Enter "1" (Yes) or "2" (No).	Required field. "." not allowed.
14. Not committed to full support?	Enter "1" if the health-care team is **NOT** committed to full support; enter "2" if the health-care team **IS** committed to full support. N.B.: Enter "2" if a patient would receive all treatments and supportive measures except for attempts at resuscitation from cardiac arrest (chest compressions, defibrillation).	Required field. "." not allowed.
15. Treated with methylxanthines (e.g., pentoxifylline, theophylline, aminophylline) within 4 hours?	Enter "1" (Yes) or "2" (No). **TREATMENT WITH METHYLXANTHINES MUST BE DISCONTINUED 4 HOURS PRIOR TO FIRST DOSE OF LSF STUDY DRUG.**	Required field. "." not allowed.
16. If aminophylline or theophylline use within 24 hours, is theophylline level ≥ 10 mg/L?	Enter "1" (Yes) or "2" (No). **THE THEOPHYLLINE LEVEL MUST BE KNOWN PRIOR TO STUDY ENTRY IF AMINOPHYLLINE OR THEOPHYLLINE WAS USED WITHIN 24 HOURS.**	Required field. "." not allowed.
17. Does patient have suspected severe, chronic liver disease?	Enter either "1" (Yes) or "2" (No). If "1", then fields A-E are required. If the sum of the values entered in A, B, C, D, and E below ≥ 10, the patient has severe chronic liver disease. Enter "1" if sum ≥ 10; enter "2" if sum < 10.	If answer to 17 is "1" (Yes) then fields A-E below are required. "." not acceptable. Otherwise, skip to item 18.
A. Ascites	Enter "1" if there are no ascites on clinical examination, "2" if ascites are present on clinical examination but not tense, or "3" if there are tense ascites.	Required field only if item 17 ="1" .

EXCLUSION FORM
(Continuation)

B. Encephalopathy	Use the system shown on the computer screen to assess the grade of encephalopathy. Enter "1" for No abnormality, "2" for Grade I or II encephalopathy, or "3" for Grade III or IV encephalopathy.	Required field only if item 17 = "1".
C. Bilirubin (mg/dL)	Enter "1" if Total Bilirubin < 2 mg/dL; enter "2" if Total Bilirubin = 2-3 mg/dL; enter "3" if Total Bilirubin > 3 mg/dL.	Required field only if item 17 = "1".
D. Albumin (g/L)	Enter "1" if serum albumin concentration > 3.5 gm/dL; enter "2" if albumin concentration = 2.8-3.5 gm/dL; enter "3" if albumin concentration < 2.8.	Required field only if item 17 =1.
E. Prothrombin time (sec prolonged).	Enter "1" if prothrombin time is prolonged < 4 seconds above control; enter "2" if prothrombin time is prolonged 5-10 seconds above control; enter "3" if prothrombin time is prolonged >10 seconds above control.	Required field only if item 17 = "1".
18. Allergy to methylxanthines? (including coffee, tea, chocolate)	Enter "1" (Yes) or "2" (No).	Required field. "." not allowed.
19. Is patient morbidly obese?	Enter "1" if actual (not ideal) body weight (kg) > body height (cm, heel to crown). Enter "2" if actual weight in kg < height in cm.	Required field. "." not acceptable.
20a. Has informed consent for the study been obtained?	Informed consent must be obtained before any study procedures are initiated. Enter "1" (yes) if study informed consent has been obtained. Enter "2" (no) if study informed consent has not been obtained.	If any item 1-19 = "1" (Yes), then do not complete items 20-24. Otherwise, 20-24 are required fields. "." not acceptable.
GENETIC TESTING	**PATIENT OR SURROGATE CAN REFUSE THEIR CONSENT FOR GENTETIC TESTING AND PARTICIPATE IN THE STUDY.**	
20b. Has consent for genetic testing been obtained?	Enter "1" (yes) if consent for genetic testing has been obtained. Enter "2" (no) if consent for genetic testing has not been obtained OR REFUSED.	Record if applicable.

EXCLUSION FORM
(continuation)

21. Enter study number # _____.	Enter the seven digit study number assigned by the coordinating center Voice Randomization System.	If any item 1-19 = "1" (Yes), then do not complete items 20-24. Otherwise, 20-24 are required fields. "." not acceptable.
22. Patient randomized to	Enter "1" if the patient was randomized to the 6 ml/kg group. Enter "2" if the patient was randomized to the 12 ml/kg group.	If any item 1-19 = "1" (Yes), then do not complete items 20-24. Otherwise, 20-24 are required fields. "." not acceptable.
23. Date/Time (military) of initial ventilator changes.	Enter the date and time (24 hour clock) of initial study ventilator changes, if any. If no ventilator changes were necessary to initiate study, enter time that ventilator changes would have been made if they were necessary.	If any item 1-19 = "1" (Yes), then do not complete items 20-24. Otherwise, 20-24 are required fields. "." not acceptable.
24. Study drug KIT number:	Enter the 6 digit KIT number from the study drug packaging.	Required field, "." not acceptable.

APACHE III - DEMOGRAPHICS
Enrollment

Complete this form on all patients enrolled into the study.

ITEM	DEFINITION	DATA RULES
1. Hospital Admission Date	Enter the date the patient was admitted to the study hospital.	Required field. "." not acceptable.
2. ICU Admission Date	Enter the date of the current ICU admission.	Required field. "." not acceptable.
3. Time of ICU Admission	Enter the time the patient was admitted to the current ICU.	Required field. "." not acceptable.
4. Patient Admitted Directly From:	Enter where the patient was **immediately prior** to this ICU admission (OR, Recovery Room, ER, Floor, Another Special Care Unit, Another Hospital, Direct Admit, Step-down Unit).	Required field. "." not acceptable.
5a. Is the patient immediately post-operative?	Answer this question with "1" (Yes) or "2" (No).	Required field. "." not acceptable.
5b. If immediately post-operative, was surgery elective?	Answer this question with "1" (Yes) or "2" (No) if surgery was in the past 24 hours. "Elective" means any surgery that is not performed in response to a life-threatening problem.	Required field if item 5a ="1".
6. ICU Readmit?	During this hospitalization, was the patient in an ICU prior to this current ICU admission?	Required field. "." not acceptable.
7. ICU Readmit within 24 hours?	If item 6 is answered "yes", was the readmission to the ICU within 24 hours of a previous ICU discharge?	Required field. "." not acceptable.
8a. Chronic Health Information Available?	Enter "1" (Yes) or "2" (No). Chronic health information may be updated at any time during the admission. **If any of the following chronic health items (items 8b-9h) are diagnosed during the hospital admission AND PRIOR to study entry, record the item as present on study entry.**	Required field. "." not acceptable. If item 8a = "2" (No), then skip 8b-9h.
8b. Is the patient on chronic dialysis or peritoneal dialysis?	Enter "1" (Yes) or "2" (No) to indicate if the patient required dialysis prior to hospitalization.	Required field only if 8a = "1" (Yes).
9a. AIDS?	Enter "1" (Yes) or "2" (No). Enter "2" (No) if HIV positive but without other AIDS criteria.	Required field only if 8a = "1" (Yes).

APACHE III - DEMOGRAPHICS
Enrollment (Continuation)

9b. Leukemia (AML, CML, all lymphocytic leuk., multiple myeloma)	Enter "1" (Yes) or "2" (No).	Required field only if 8a = "1" (Yes).
9c. Non-Hodgkin's Lymphoma	Enter "1" (Yes) or "2" (No).	Required field only if 8a = "1" (Yes).
9d. Solid Tumor with metastasis	Enter "1" (Yes) or "2" (No).	Required field only if 8a = "1" (Yes).
9e. Immune Suppression	Enter "1" (Yes) or "2" (No) to indicate if the patient is immunocompromised secondary to chemotherapy, radiation therapy, use of anti-rejection drugs taken after organ transplant, or the daily use of high doses of steroids (0.3 mg Prednisone kg/day or equivalent therapy) within part of or the entire previous six months.	Required field only if 8a = "1" (Yes).
9f. Hepatic Failure	Enter "1" (Yes) or "2" (No) to indicate if the patient has decompensated cirrhosis (Hepatic Failure) as evidenced by one or more episodes of jaundice and ascites, upper gastrointestinal bleeding or hepatic encephalopathy or comas.	Required field only if 8a = "1" (Yes).
9g. Compensated cirrhosis.	Enter "1" (Yes) or "2" (No) to indicate if the patient has cirrhosis without the stigmata indicated above in 9f. If the patient has a functioning liver transplant, this chronic health item would not apply.	Required field only if 8a = "1" (Yes).
9h. Diabetes Mellitus	Enter "1" (Yes) or "2" (No).	Required field only if 8a = "1" (Yes).

APACHE III PHYSIOLOGY
Enrollment

COMPLETE ON DAY 0. ALL DATA SHOULD BE TAKEN FROM THE 24 HOURS PRECEDING INITIAL VENTILATOR CHANGES (IF ANY). DO NOT INCLUDE INTRAOPERATIVE VALUES OR VALUES RELATED TO DEATH OR CARDIO/RESPIRATORY ARREST SITUATIONS.

For items on this table indicated with "*" (items 8-18), if no values were obtained for clinical purposes during the 24 hours preceding initial study procedures, the lab tests must be obtained before initiating study procedures.

ITEM	DEFINITION	DATA RULES
1. Temperature	Enter the highest and lowest temperatures in Centigrade or Fahrenheit. Add 1 degree Centigrade or 2 degrees Fahrenheit if axillary temperatures.	Required field. "." not acceptable.
2. Systolic BP	Enter the highest and lowest.	Required field. "." not acceptable.
3. Mean Arterial Pressure	Enter the highest and lowest.	Required field. "." not acceptable.
4. Heart Rate	Enter the highest and the lowest.	Required field. "." not acceptable.
5. Respiratory Rate	Enter the highest and the lowest.	Required field. "." not acceptable.
6. Was patient ventilated with worst respiratory rate?	Enter "1" (Yes) or "2" (No). If the same worst RR occurred both on and off ventilator, enter "2".	Required field. "." not acceptable.
7. Urine Output 24 hr	Enter the amount of **urine** output (ml) in the 24 hrs prior to initial ventilator changes (if any). E.g., if initial ventilator changes occur on 2/1/96 at 1400, then the urinary output listed should be from 1/31/96 at 1400 to 2/1/96 at 1400).	Required field.
8 Hematocrit*	Enter highest and lowest values as "00.0" (e.g., "35.2", not " .352"). If only one value present for 24 hour period, enter this value as both the highest and lowest.	Required field. "." not acceptable.
9. WBC* (White Blood Cell count).	Enter highest and lowest as "00000" (e.g., a WBC of 14,200 should be entered as "14200" Do not add comma.). If only one value present for 24 hour period, enter it as both the highest and lowest.	Required field. "." not acceptable.
10. Platelets*	Enter only the lowest value during the 24 hours. Enter as "000" (e.g., a platelet count of 258,000 should be entered as "258".	Required field. "." not acceptable.

APACHEE III PHYSIOLOGY
Enrollment (Continuation)

11. Serum Sodium*	Enter highest and lowest. If only one value present for 24 hour period, it should be entered as both the highest and lowest.	Required field. "." not acceptable.
12. Serum Potassium*	Enter highest and lowest. If only one value present for 24 hour period, it should be entered as both the highest and lowest.	Required field. "." not acceptable.
13. Serum BUN*	Enter only highest value.	Required field. "." not acceptable.
14. Serum Creatinine*	Enter highest and lowest. If only one value present for 24 hour period, it should be entered as both the highest and lowest.	Required field. "." not acceptable.
15. Serum Glucose*	Enter highest and lowest. If only one value present for 24 hour period, it should be entered as both the highest and lowest.	Required field. "." not acceptable.
16. Serum Albumin*	Enter highest and lowest. If only one value present for 24 hour period, it should be entered as both the highest and lowest.	Required field. "." not acceptable.
17. Serum Bilirubin*	Enter only highest value.	Required field. "." not acceptable.
18. Serum Bicarbonate*	Enter only lowest value.	Required field. "." not acceptable.

APACHE ARTERIAL BLOOD GASES
Enrollment

Record ALL ABG's in the 24 hours preceding initial study ventilator changes, if any. Record "Yes" or "No" if the patient was intubated (with or without positive pressure ventilation) when each ABG was obtained.

FiO_2	PaO_2	$PaCO_2$	pH	Intubated?	DATA RULES
1.					Required field. "." not acceptable.
2.					Record values, if available.
3.					Record values, if available.
4.					Record values, if available.
5.					Record values, if available.
6.					Record values, if available.
7.					Record values, if available.
8.					Record values, if available.
9.					Record values, if available.
10.					Record values, if available.

VITAL SIGNS DAY-0

VALUES FOR ITEMS 2-5 SHOULD BE OBTAINED IN THE 4 HOUR INTERVAL THAT PRECEDES INITIAL VENTILATOR CHANGES AND BEFORE LSF STUDY DRUG ADMINISTRATION. IF MORE THAN ONE VALUE IS AVAILABLE DURING THIS INTERVAL, RECORD THE VALUE CLOSEST TO THE TIME OF INITIAL VENTILATOR CHANGE.

AN EXCEPTION TO THIS RULE IS THE PATIENT'S HEIGHT. IT MUST BE MEASURED AND RECORDED IN THE PATIENT'S RECORD PRIOR TO PLACING THE CALL FOR RANDOMIZATION. THE ENTRY FOR HEIGHT MUST BE DATED AND TIMED IN THE PATIENT'S RECORD

Values for other items may be obtained during the 24 hour interval preceding initial ventilator change. If no values were obtained for clinical purposes (items 12-27) during this interval, a blood specimen should be drawn and sent prior to the time of initial ventilator change. If more than one value is available, use the most recent value before the time of initial ventilator change.

ITEM	DEFINITION	DATA RULES
1. Date and Time of current intubation:	Enter the date and time (24 hour clock) when the qualifying intubation was performed.	Required field. "." not acceptable.
2. Heart Rate.	Use last value prior to study initiation.	Required field. "." not acceptable.
3. Systolic BP.	Use last value prior to study initiation. The systolic value must be taken from the same time as the diastolic value in #4.	Required field. "." not acceptable.
4. Diastolic BP.	Use last value prior to study initiation. If diastolic BP cannot be obtained (e.g. when BP is palpable but not audible or when doppler is used to measure systolic pressure), enter "." The diastolic value must be taken from the same time as the systolic value in #3.	Required field. "." not acceptable.
5. Temperature	Use last value prior to study initiation. Prefer rectal, tympanic, or core temperature. If axillary used, add 1 degree Centigrade or 2 degrees Fahrenheit.	Required field. "." not acceptable.
6. Height	Record patient's height from heel to crown. Patient should be supine with legs straight (no flexion or extension of hips and knees, if possible), during measurement.	Required field. "." not acceptable.
7. Gender	Enter "1"=Male, "2"=Female	Required field. IBW computation requires this information.

VITAL SIGNS DAY-0
(Continuation)

8. IBW	Value for Ideal Body Weight in kilograms will be computed based on gender and height. Males: IBW = 50 + 2.3(inches - 60) Female: IBW = 45.5 + 2.3(inches - 60)	Computer generated. Must have entered both gender and height in order for computer to generate number
9. Weight	Enter most recent measured body weight. If weight not available during preceding 24 hours, enter most recent weight..	Required field.
10. Fluid Intake:	Enter total amount of fluids (parenteral and enteral) measured/recorded during the 24 hours that preceded the initial ventilator changes.	Collect data, when available. "." is allowed
11. Urine Output::	Enter total amount of **urine** output measured/recorded during the 24 hours that preceded the initial ventilator changes.	Collect data, when available. "." is allowed
12. Hct::	Enter value as "00.0" (e.g., 39.3). If none in 24 hours prior to study initiation, send blood specimen.	Required field. "." not acceptable.
13. WBC:	Enter value as "00000" (e.g., if WBC = 14,200, enter "14200". Do not use comma. If none in 24 hours prior to study initiation, send blood specimen.	Required field. "." not acceptable.
14. AST (SGOT)	Record most recent value. If none in 24 hours prior to study initiation, send blood specimen.	Required field. "." not acceptable.
15. ALT (SGPT)	Record most recent value. If none in 24 hours prior to study initiation, send blood specimen.	Required field. "." not acceptable.
16. Alkaline Phosphatase	Record most recent value. If none in 24 hours prior to study initiation, send blood specimen.	Required field. "." not acceptable.
17. Platelets:	Enter as "000" (e.g., a platelet count of 258,000 should be entered as "258".)	Required field. "." not acceptable.
18. Bilirubin:	Record most recent value (mg/dL). If none in 24 hours prior to study initiation, send blood specimen.	Required field. "." not acceptable.

VITAL SIGNS DAY-0
(Continuation)

19. Albumin:	Record most recent value (g/dL). If none in 24 hours prior to study initiation, send blood specimen.	Required field. "." not acceptable.
20. Sodium:	Record most recent value (mEq/L). If none in 24 hours prior to study initiation, send blood specimen.	Required field. "." not acceptable.
21. Potassium:	Record most recent value (mEq/L). If none in 24 hours prior to study initiation, send blood specimen.	Required field. "." not acceptable.
22. Glucose:	Record most recent value (mg/dL). If none in 24 hours prior to study initiation, send blood specimen.	Required field. "." not acceptable.
23. Creatinine:	Record most recent value (mg/dL). If none in 24 hours prior to study initiation, send blood specimen.	Required field. "." not acceptable.
24. BUN:	Record most recent value (mg/dL). If none in 24 hours prior to study initiation, send blood specimen.	Required field. "." not acceptable.
25: Chloride:	Record most recent value (mEq/L). If none in 24 hours prior to study initiation, send blood specimen.	Required field. "." not acceptable.
26: HCO3 (bicarbonate):	Record most recent value (mEq/L). If none in 24 hours prior to study initiation, send blood specimen.	Required field. "." not acceptable.
27. Hgb (hemoglobin):	Record most recent value (g/dL). If none in 24 hours prior to study initiation, send blood specimen.	Required field. "." not acceptable.
28. HCG (pregnancy):	Obtain HCG (mIU/mL) on all female patients of reproductive age. Must have results prior to study enrollment.	Required field for all women of reproductive potential.

BASELINE VENTILATOR PARAMETERS
Enrollment

The following information should be taken from the four-hour interval that immediately precedes initial study ventilator changes, if any. If more than one value is available during this four-hour interval, enter the last value prior to initial study ventilator changes.

EXCEPTIONS TO THIS RULE ARE: THE CALCULATED DELIVERED TITAL VOLUME, PEEP, AND PSTAT; WHICH MUST BE MEASURED AND RECORED IN THE RESPIRATORY THERAPY FLOW SHEET PRIOR TO PLACING THE CALL FOR RANDOMIZATION. THESE ENTRIES INTO THE FLOWSHEET MUST BE DATED AND TIMED.

ITEM	DEFINITION	DATA RULES
1. Ventilator manufacturer and model	Enter the appropriate number to indicate if the patient is on a Puritan 7200, Servo 9000, Servo 300, Hamilton Veolar/Amadeus, Bird 8400, Bear 1000, or other ventilator.	Required field. "." not acceptable.
2. Ventilator mode	Enter "1" (Yes) or "2" (No) for each of the four modes shown (SIMV, Pressure Support, Assist/Control, Pressure Control, PCIRV, Other. If the patient was on SIMV with PS, enter "1" (Yes) for both "SIMV" and "Pressure Support".	Required field. "." not acceptable.
3. Calculated delivered tidal volume	Enter the inspired tidal volume (ml) set on the ventilator.	Required field if item #2, 2.1 or 2.3 = "1" (Yes)
4. Pressure Control Level	Enter the pressure control level (cm H_2O) on the ventilator if the patient is on Pressure Control Ventilation or PCIRV.	Required field if item #2, 2.4 or 2.5 = "1" (Yes)
5. Pressure Support	Enter the level of Pressure Support (in cmH_2O) if the patient is receiving pressure support ventilation either in the Pressure Support or SIMV with Pressure Support mode. The Pressure Support level indicates the increment in airway pressure during inspiration above its level during expiration. For example, if PEEP = 5 and inspired airway pressure = 20, then enter Pressure Support = 15.	Required field if item #2, 2.2 = "1" (Yes)
6. Set Rate	Enter the rate set on the ventilator if the patient is on the SIMV, SIMV with Pressure Support, Assist/Control, or Pressure Control mode. (This is the minimum rate set on the ventilator, not the patient rate).	Required field if item #2, 2.1, 2.3, 2.4 or 2.5 = "1" (Yes)

BASELINE VENTILATOR PARAMETERS
Enrollment (Continuation)

7. Total Respiratory Rate	Enter the total respiratory rate, which may exceed the Set Rate above if the patient is making additional inspiratory efforts.	Required field. "." not acceptable.
8. Total Minute Ventilation	Enter the total minute ventilation in liters per minute. This value is available from a digital report on the ventilator.	Required field. "." not acceptable.
9. PEEP	Enter the PEEP applied on the ventilator in cmH_2O. This is the external or applied PEEP, not the total PEEP, auto-PEEP, or intrinsic PEEP.	Required field. "." not acceptable.
10. Plateau Pressure	The plateau pressure measurement should be made with a 0.5 second inspiratory pause.	Required field if item #2, 2.1 or 2.3 = "1" (Yes)
11. Peak Inspiratory Pressure	Enter the peak inspiratory airway pressure (cmH_2O). This should be obtained while the patient is relaxed, not coughing or moving in bed.	Required field if item #2, 2.1 or 2.3 = "1" (Yes)
12. I:E Ratio	Enter the ratio of the duration of inspiration to expiration. Monitor the I:E ratio for at least one minute and enter a representative value.	Required item. "." not acceptable.
13. Mean Airway Pressure	Enter the mean airway pressure (cmH_2O). This should be obtained while the patient is relaxed, not coughing or moving in bed.	Required item. "." not acceptable.
14. FiO_2	Enter the fraction of inspired oxygen as decimal (e.g., ".50", not 50%)	Required item. "." not acceptable.
15,16,17: PaO_2, $PaCO_2$, and Arterial pH	Enter results of the last arterial blood gas prior to initial study ventilator changes, if any.	Required item. "." not acceptable.
18. SpO_2	Enter pulse oximetry value prior to study ventilator changes, if any. Observe the oximeter values for at least one minute and enter a representative value.	Required item. "." not acceptable.

CHEST X-RAY/BAROTRAUMA
Enrollment

Use the most recent chest radiograph prior to initial ventilator changes, if any. Qualifying radiographs must be interpreted by a Network Principal Investigator or designee.

ITEM	DEFINITION	DATA RULES
1. Radiographic Lung Injury Score	Enter a number from 0 through 4 that indicates the number of quadrants with pulmonary infiltrate. Shadows interpreted as infiltrates may not be caused by effusions, atelectasis, masses, indistinct or plump blood vessels, or shadows known to be chronic.	Required field. "." not acceptable.
2a. Pneumothoraces	Enter the appropriate numerical code to indicate if there is a pneumothorax on the right side (1), on the left side (2), on both sides, bilateral (3), or none (4).	Required field. "." not acceptable.
2b. Subcutaneous emphysema	Indicate with "1" (Yes) or "2" (No) if there is subcutaneous emphysema apparent on the chest x-ray that is attributed to barotrauma.	Required field. "." not acceptable.
2c. Pneumomediastinum	Indicate with "1" (Yes) or "2" (No) if the chest x-ray shows air in the mediastinum attributed to barotrauma.	Required field. "." not acceptable.
2d. Pneumatoceles > 2 cm diameter	Indicate if there are one or more pneumatoceles > 2 cm minimum diameter (a bubble or hole in the parenchyma that is not attributed to a chronic bleb or bullous lesion), on the right side (1), the left side (2), on both sides, bilateral (3), or on neither side.	Required field. "." not acceptable.
3. Chest Tube	Indicate if there are one or more chest tubes on the right side (1), on the left side (2), on both sides (3), or on neither side (4).	Required field. "." not acceptable.

MEDICATIONS-Enrollment

Complete this form using information pertaining to the 24 hour interval that precedes the initial ventilator changes.
For item #1, use information pertaining to the 72 hours prior to initial ventilator changes.

ITEM	DEFINITION	DATA RULES
1. Did chart review reveal an infection within 72 hours prior to enrollment?	Enter "1" (Yes) or "2" (No) to indicate if the patient has a pre-existing infection prior to study enrollment. (Study enrollment is defined as the time of initial ventilator change.) If yes, complete the appropriate infection or bacteremia forms accessible under the ALL menu.	Required field.
2. Sedatives/ Tranquilizers (benzodiazepines, narcotics, barbiturates, propofol, or other medications given for sedation)	Enter "1" (Yes) or "2" (No) to indicate if the patient received any amount of the listed medications in the 24 hours prior to study initiation.	Required field.
3. Neuromuscular Blocking Agents	Enter "1" (Yes) or "2" (No) to indicate if patient has received pancuronium, vecuronium, atracurium, succinylcholine, or other medication for neuromuscular blockade (paralysis) within 24 hours prior to study initiation.	Required field.
4. Antifungal Imidazole (e.g. Fluconazole)	Enter "1" (Yes) or "2" (No).	Required field.
5. Amphotericin	Enter "1" (Yes) or "2" (No) if the patient received intravenous amphotericin.	Required field.
6. Aminoglycosides	Enter "1" (Yes) or "2" (No). If Yes, select the antibiotic from the list and enter the corresponding number(s) in the field(s).	Required field.
7.Cephalosporins	Enter "1" (Yes) or "2" (No). If Yes, select the antibiotic from the list and enter the corresponding number(s) in the field(s).	Required field.
8. Macrolides	Enter "1" (Yes) or "2" (No). If Yes, select the antibiotic from the list and enter the corresponding number(s) in the field(s). Examples include erythromycin and clarithromycin (Biaxin).	Required field.

MEDICATIONS-Enrollment
(Continuation)

9. Penicillins	Enter "1" (Yes) or "2" (No). If Yes, select the antibiotic from the list and enter the corresponding number(s) in the field(s). Examples include ampicillin, piperacillin, mezlocillin and ticarcillin. Also include penicillins mixed with sulbactam or clavulanic acid (e.g., ticarcillin + clavulanic acid = Timentin).	Required field.
10. Quinolones	Enter "1" (Yes) or "2" (No). If Yes, select the antibiotic from the list and enter the corresponding number(s) in the field(s). Examples include ofloxacin, ciprofloxacin.	Required field.
11. Vancomycin	Enter "1" (Yes) or "2" (No).	Required field.
12. Other Antibiotic	Enter "1" (Yes) or "2" (No). Enter yes only if the antibiotic does not belong to the above broad classifications of antibiotics.	Required field.
13. Antipsychotics (e.g. haloperidol, droperidol)	Enter "1" (Yes) or "2" (No).	Required field.
14. Nitric Oxide	Enter "1" (Yes) or "2" (No).	Required field.
15. Prone Positioning	Enter "1" (Yes) or "2" (No).	Required field.
16. Antivirals	Enter "1" (Yes) or "2" (No). Include acyclovir, AZT and other anti-HIV agents, rimantadine, amantadine, and CMV immune globulin.	Required field.
16. Methylxanthines (e.g. theophylline, pentoxifylline or aminophylline)	Enter "1" (Yes) or "2" (No) to indicate if patient has received any methylxanthines. **TREATMENT WITH METHYLXANTHINES MUST BE DISCONTINUED 4 HOURS PRIOR TO FIRST DOSE OF LSF STUDY DRUG. THEOPHYLLINE DRUG LEVELS MUST BE <10 mg/L IF GIVEN WITHIN 24 HOURS OF FIRST LSF STUDY DRUG DOSE.**	Required field.

12-LEAD ECG- Enrollment

Record ECG from the 24 hour interval prior to the first study drug infusion. If more than one, use most recent.

Heart Rate:	Enter the ventricular rate in beats per minute.	Required field.
CARDIAC CYCLE MEASURMENTS		
P-R interval	Enter time in seconds.	Required field.
QRS interval	Enter time in seconds.	Required field.
Q-T interval	Use absolute Q-T in seconds (not corrected Q-T).	Required field.
Interpretation:	Enter "1" =Within normal limits, "2"=Abnormal	Required field. "." not acceptable.

FIRST DOSE VITAL SIGNS

Record vital signs immediately prior to; at completion, and 30 minutes after completion of the FIRST LSF study drug dose.

ITEM	DEFINITION	DATA RULES
FIRST DOSE PRE-INFUSION VITAL SIGNS:	Enter time (military) that pre-infusion vital signs were taken, immediately prior to the FIRST study drug dose.	Required field.
1. Heart Rate:		Required field.
2. Systolic BP:		Required field.
3. Diastolic BP:		Required field.
4. Temperature:	Rectal, tympanic, or core temperature preferred. If axillary temperature used, add 1° C or 2° F.	Required field.
FIRST DOSE POST-INFUSION VITAL SIGNS:	Enter time (military) that post infusion vital signs were taken, at completion of study dose infusion.	Required field.
1. Heart Rate:		Required field.
2. Systolic BP:		Required field.
3. Diastolic BP:		Required field.
4. Temperature:	Rectal, tympanic, or core temperature preferred. If axillary temperature used, add 1° C or 2° F.	Required field.
FIRST DOSE 30 MINUTE POST-INFUSION VITAL SIGNS:	Enter time (military) that vital signs were taken, 30 minutes after completion of the FIRST study drug infusion.	Required field.
1. Heart Rate:		Required field.
2. Systolic BP:		Required field.
3. Diastolic BP:		Required field.
4. Temperature:	Rectal, tympanic, or core temperature preferred. If axillary temperature used, add 1° C or 2° F.	Required field.

DRUG DOSING/SPECIMEN LOG-DAY 0

Complete this form for the infusion of all doses of Lisofylline study drug for this calendar day.

1a. Start time of infusion: ***(*Complete first dose vital signs form at this time.)***	Enter the ACTUAL time (military) that the infusion of the FIRST dose started.	Required field.
1b. Dosage:	Enter first dose in milligrams.	Required field.
2a. Start time of infusion:	Enter the ACTUAL time (military) that infusion of the SECOND dose started.	Required field.
2b. Dosage:	Enter second dose in milligrams.	Required field.
3a. Start time of infusion:	Enter the ACTUAL time (military) that infusion of the THIRD dose started.	Required field.
3b. Dosage:	Enter third dose in milligrams.	Required field.
4a. Start time of infusion:	Enter the ACTUAL time (military) that infusion of the FOURTH dose started.	Required field.
4b. Dosage:	Enter fourth dose in milligrams.	Required field.
5a. Start time of infusion:	Enter the ACTUAL time (military) that infusion of the FIFTH dose started. **This field is to be used for instances when a "midnight" dose is actually given prior to 2400, resulting in 5 doses being given on one calendar day.**	Record if available.
5b. Dosage:	Enter fifth dose in milligrams.	Record if available.
PHARMACOKINETICS:	SPECIMEN COLLECTION: LSF STUDY DRUG LEVELS SHOULD BE DRAWN WITHIN **30 MINUTES** BEFORE AND WITHIN **ONE MINUTE** AFTER COMPLETION OF THE FIRST INFUSION: 1) Draw 4.5 ml of blood via arterial line, venous line, or venipuncture and fill one 4.5 ml blue-top tube (containing buffered sodium citrate). SAMPLES SHOULD NOT BE DRAWN FROM THE SAME LINE THROUGH WHICH THE STUDY DRUG WAS INFUSED. 2) Samples should be placed on ice and stored in the refrigerator no longer than 2 hours before the sample is processed. 3) Plasma should be prepared by centrifugation and aliquoted into a 4.5 ml polypropylene tube. (Pre-labeled tubes and collection records will be provided by the repository.) 4) Plasma samples should be stored in a freezer set to -20° C.	
6a. Pre-infusion draw?	Enter "1"=Yes, "2"=No.	Required field.
6b If yes, give time:	Enter time (military).	Required field, if 6a=Yes

DRUG DOSING/SPECIMEN LOG-DAY 0
(Continuation)

7a. Post-infusion draw?	Enter "1"=Yes, "2"=No.	Required field.
7b. If yes, give time:	Enter time (military).	Required field if 7a =Yes.
7c. Stop time of infusion:	Enter time (military) that the study drug infusion was completed.	Required field.
SURROGATE MARKERS:	SPECIMEN COLLECTION: WITHIN 30 MINUTES BEFORE INFUSION OF THE FIRST DOSE OF LSF STUDY DRUG: 1) Collect two 10.0 ml blood samples, 1 in a 10 ml green top vacutainer tube (sodium heparin) and 1 in a 10 ml red top tube. 2) Place the samples immediately on ice and process WITHIN 2 HOURS OF COLLECTION. 3) Plasma (green top) should be prepared by centrifugation and aliquoted evenly into **four** 1.5 ml polypropylene tubes and should be stored in a freezer set to -20° C. 4) Serum (red top) should also be prepared by centrifugation and evenly aliquoted into **four** 1.5 ml polypropylene tubes and stored in a freezer set to -20° C.	
8a. Pre-infusion draw?	Enter "1"=Yes, "2"=No.	Required field.
8b. If yes, give time:	Enter time (military).	Required field, if 8a=Yes

FOR DAY 0 CYTOKINES, SEE SPECIMEN COLLECTION IN "ALL" MENU.

GLASGOW COMA SCORE: DAY 0

Complete this form using the worst values for the 24 hour interval preceding initial study ventilator changes, if any.

ITEM	DEFINITION	DATA RULES
1. Sedatives or Neuromuscular Blocking Agents.	1. Enter "1" (Yes) or "2" (No) to indicate if the patient received any sedative or any neuromuscular blocking agent during the 24 hour interval preceding initial study ventilator changes, if any. If "Yes", then make best estimates for the values below assuming the patient had not received any of these medications.	Required field.
Glasgow Coma Score (GCS)	Use the worksheet provided to calculate the worst GCS within 24 hours prior to initial study ventilator changes, if any. All three components should originate from the same time point.	
2. Eye Opening Score	Enter a value (1,2,3, or 4) to indicate best response. If patient's eyes are swollen shut, estimate best response.	Required field.
3. Motor Response Score	Enter a value (1,2,3,4,5, or 6) to indicate best response.	Required field.
4. Verbal Response Score	Enter a value (1,2,3,4, or 5) to indicate best response. If patient was intubated for 24 hours prior to initial study procedures, use clinical judgment to estimate best response. If unsure, enter "3".	Required field.
5. GCS (total)	Computer calculated total Glasgow Coma Score.	Computer generated.

ON STUDY VITAL SIGNS

Fill out this form and send the required laboratory tests (items 8-23) on the following study days: 1, 2, 3, 4, 7, 14, 21. If the patient achieves 48 hours of Unassisted Breathing before Day 20, discontinue LSF study drug, fill out the next scheduled on study vital signs form, and draw the next scheduled labs.

If clinically obtained laboratory test results are available within one calendar date of the above protocol-specified days, then these values can be used.

ITEMS 1-4 ARE REQUIRED DURING THE REFERENCE PERIOD 0600-1000 ON THE CALENDAR DATE. IF MORE THAN ONE VALUE IS AVAILABLE FROM 0600-1000, RECORD THE VALUE CLOSEST TO 0800.

ALSO RECORD THE HIGHEST AND LOWEST VALUES THIS CALENDAR DATE (MAY INCLUDE VALUES FROM THE REFERENCE PERIOD).

FOR ITEMS 5-23, USE VALUES DURING INTERVAL FROM 0600-1000 (RECORD THE VALUE CLOSEST TO 0800 IF MORE THAN ONE), IF AVAILABLE. IF VALUES ARE NOT AVAILABLE FROM 0600-1000, USE VALUES CLOSEST TO 0600-1000 ON THIS CALENDAR DATE.

ITEM	DEFINITION	DATA RULES
1. Heart Rate	Enter value recorded between 0600-1000, closest to 0800 if more that one. For highest/lowest values, record minimum and maximum values for this calendar date.	Required field. "." not acceptable.
2. Systolic BP (take value from the same time as the diastolic value in #3).	Enter value recorded between 0600-1000, closest to 0800 if more than one. For highest/lowest values, record the **MAXIMUM** value only for this calendar date.	Required field. "." not acceptable.
3. Diastolic BP (take value form the same time as the systolic value in #4).	Enter value recorded between 0600-1000, closest to 0800 if more than one. If diastolic pressure not available because pressure is measurable only by palpation or doppler, enter "." (highest/lowest values not required for this value).	Required field but "." is allowed.
4. Temperature	Rectal, tympanic, or core temperature preferred. If axillary temperature used, add 1° C or 2° F. For highest/lowest values, record minimum and maximum values for this calendar date.	Required field. "." not acceptable.
5. Weight	Enter actual body weight measured on this date, if available.	Required field but "." is allowed.
6. Fluid Intake	Record total fluid intake (parenteral and enteral) during 24 hours preceding reference period (i.e., may use 24 hour totals from previous calendar day).	Required field. "." not acceptable.

ON STUDY VITAL SIGNS
(Continuation)

7. Urine Output	Record total **urine** output during 24 hours preceding reference period (i.e., may use 24 hour totals from previous calendar day).	Required field. "." not acceptable.
8. Hematocrit	Enter value as "00.0".	Required field. "." not acceptable.
9. WBC	Record white blood cell count as "00000" (e.g., if WBC = 14,300, enter as "14300". Do not use a comma).	Required field. "." not acceptable.
10. AST (SGOT)	Record value in U/L.	Required field. "." not acceptable.
11. ALT (SGPT)	Record value in U/L.	Required field. "." not acceptable.
12. Alkaline Phosphatase	Record value in U/L.	Required field. "." not acceptable.
13. Platelets:	Enter as "000" (e.g., a platelet count of 258,000 should be entered as "258".)	Required field. "." not acceptable.
14. Bilirubin:	Record value in mg/dL.	Required field. "." not acceptable.
15. Albumin:	Record value in g/dL.	Required field. "." not acceptable.
16. Sodium:	Record value in mEq/L..	Required field. "." not acceptable.
17. Potassium:	Record value in mEq/L..	Required field. "." not acceptable.
18. Glucose:	Record value in mg/dL..	Required field. "." not acceptable.
19. Creatinine:	Record value in mg/dL..	Required field. "." not acceptable.
20. BUN:	Record value in mg/dL.	Required field. "." not acceptable.
21: Chloride:	Record value in mEq/L..	Required field. "." not acceptable.
22: HCO3 (bicarbonate):	Record value in mEq/L..	Required field. "." not acceptable.
23. Hgb (hemoglobin):	Record value in g/dL.	Required field. "." not acceptable.

ON STUDY VENTILATOR PARAMETERS
STUDY DAYS: 1, 2, 3, 4, 7, 14, 21, and 28

Complete this form on the study days shown above if the patient has not died or achieved 48 hours of unassisted breathing. Record data from the Reference Interval from 0600-1000. When more than one value is available during this interval, record the value closest to 0800. Discontinue this form after the patient has achieved 48 hours of unassisted breathing.

ITEM	DEFINITION	DATA RULES
1. Ventilator manufacturer and model	Enter the appropriate number to indicate if the patient is on a Puritan 7200, Servo 9000, Servo 300, Hamilton Veolar/Amadeus, Bird 8400, Bear 1000, or other ventilator.	Required field. "." not acceptable.
2. Ventilator mode	Enter "1" (Yes) or "2" (No) for each of the three modes shown (Assist/Control, Pressure Support, Unassisted Breathing).	Required field. "." not acceptable.
3. Calculated delivered tidal volume	Enter the inspired tidal volume (ml) set on the ventilator.	Required field if item #2, 2.1 = "1" (Yes)
4. Pressure Support	Enter the level of Pressure Support (in cmH_2O) if the patient is receiving pressure support ventilation. The Pressure Support level indicates the increment in airway pressure during inspiration above its level during expiration. For example, if PEEP = 5 and inspired airway pressure = 20, then enter Pressure Support = 15.	Required field if item #2, 2.2 = "1" (Yes)
5. Set Rate	Enter the rate set on the ventilator if the patient is on Assist/Control. (This is the minimum rate set on the ventilator, not the patient rate).	Required field if item #2, 2.1 = "1" (Yes)
6. Total Respiratory Rate	Enter the total respiratory rate, which may exceed the Set Rate above if the patient is making additional inspiratory efforts.	Required field. "." not acceptable.
7. Total Minute Ventilation	Enter the total minute ventilation in liters per minute. This value is available from a digital report on the ventilator.	Required field if item #2, 2.1 or 2.2 = "1" (Yes)

ON STUDY VENTILATOR PARAMETERS
(Continuation)

8. PEEP	Enter the PEEP applied on the ventilator in cmH_2O. This is the external or applied PEEP, not the total PEEP, auto-PEEP, or intrinsic PEEP.	Required field if item #2, 2.1 or 2.2 = "1" (Yes)
9. Plateau Pressure	The plateau pressure measurement should be made with a 0.5 second inspiratory pause	Required field only if item #2, 2.1 = "1" (Yes) .
10. Peak Inspiratory Pressure	Enter the peak inspiratory airway pressure (cmH_2O). This should be obtained while the patient is relaxed, not coughing or moving in bed.	Required field only if item #2, 2.1 = "1" (Yes) .
11. I:E Ratio	Enter the ratio of the duration of inspiration to expiration. Monitor the I:E ratio for at least one minute and enter a representative value.	Required field only if item #2, 2.1 = "1" (Yes) .
12. Mean Airway Pressure	Enter the mean airway pressure (cmH_2O). This should be obtained while the patient is relaxed, not coughing or moving in bed.	Required field only if item #2, 2.1 = "1" (Yes) .
13. FiO_2	Enter the fraction of inspired oxygen as decimal (e.g., ".50", not 50%)	Required item. "." not acceptable.
14., 15, 16. PaO_2, $PaCO_2$, and Arterial pH	Enter results of Arterial Blood Gas analysis. If no ABG obtained during the 6-10 reference period, record closest value available this calendar day.	
17: SpO_2:	Enter pulse oximetry value if available. Observe the oximeter values for at least one minute and enter a representative value.	

CHEST X-RAY/BAROTRAUMA
STUDY DAYS: 1, 2, 3, 4, 7, 14, 21, 28

Complete this form on the study days shown above if the patient is alive but has not achieved 48 hours of unassisted breathing. Use the first chest x-ray obtained during the Reference Interval 0600-1000. If no chest x-ray was obtained during this interval, use the first x-ray obtained on this calendar date. If no chest x-ray was obtained on this calendar date, do not complete this form.

ITEM	DEFINITION	DATA RULES
1. Radiographic Lung Injury Score	Enter a number from 0 through 4 that indicates the number of quadrants with pulmonary infiltrate. Shadows interpreted as infiltrates may not be caused by effusions, atelectasis, masses, indistinct or plump blood vessels, or shadows known to be chronic.	Required field. "." is allowed.
2a. Pneumo-thoraces	Enter the appropriate numerical code to indicate if there is a pneumothorax on the right side (1), on the left side (2), on both sides, bilateral (3), or none (4).	Required field. "." is allowed.
2b. Subcutaneous emphysema	Indicate with "1" (Yes) or "2" (No) if there is subcutaneous emphysema apparent on the chest x-ray that is attributed to barotrauma.	Required field. "." is allowed.
2c. Pneumo-mediastinum	Indicate with "1" (Yes) or "2" (No) if the chest x-ray shows air in the mediastinum attributed to barotrauma.	Required field. "." is allowed.
2d. Pneumatoceles > 2 cm diameter	Indicate if there are one or more pneumatoceles > 2 cm minimum diameter (a bubble or hole in the parenchyma that is not attributed to a chronic bleb or bullous lesion), on the right side (1), the left side (2), on both sides, bilateral (3), or on neither side (4).	Required field. "." is allowed.
3. Chest Tube	Indicate if there are one or more chest tubes on the right side (1), on the left side (2), on both sides (3), or on neither side (4).	Required field. "." is allowed.

MONITORING AND MEDICATION REPORT
STUDY DAYS: 1- 28

Complete this form on the study days shown above if the patient is alive and receiving mechanical ventilation or is attempting a 48 hour period of unassisted breathing.

ITEM	DEFINITION	DATA RULES
1. Chart review suggests infection this calendar day?	Enter "1" (Yes) or "2" (No) to indicate if the patient has an infection. If Yes, complete the appropriate infection form accessible under the Day All menu.	Required field.
2. Do clinicians suspect new nosocomial pneumonia?	Enter "1" (Yes) or "2" (No) to indicate if a new nosocomial pneumonia is suspected by the patient's clinicians. This information may be obtained through chart review, discussion with clinicians, etc.	Required field.
3. Sedative/Tranquilizers (benzodiazepines, narcotics, barbiturates, propofol)	Enter "1" (Yes) or "2" (No) to indicate if the patient received any amount of the listed medications.	Required field.
4. Neuromuscular Blocking Agents	Enter "1" (Yes) or "2" (No) to indicate if patient has received pancuronium, vecuronium, atracurium, succinylcholine, or other medication for neuromuscular blockade .	Required field.
5. Antifungal Imidazole (e.g. Fluconazole)	Enter "1" (Yes) or "2" (No).	Required field.
6. Amphotericin	Enter "1" (Yes) or "2" (No) if the patient received intravenous amphotericin.	Required field.
7. Aminoglycosides	Enter "1" (Yes) or "2" (No). If Yes, select the antibiotic from the list and enter the corresponding number(s) in the field(s).	Required field.
8.Cephalosporins	Enter "1" (Yes) or "2" (No). If Yes, select the antibiotic from the list and enter the corresponding number(s) in the field(s).	Required field.
9. Macrolides	Enter "1" (Yes) or "2" (No). If Yes, select the antibiotic from the list and enter the corresponding number(s) in the field(s). Examples include erythromycin and clarithromycin (Biaxin).	Required field.

MONITORING AND MEDICATION REPORT
STUDY DAYS: 1- 28
(Continuation)

10. Penicillins	Enter "1" (Yes) or "2" (No). If Yes, select the antibiotic from the list and enter the corresponding number(s) in the field(s). Examples include ampicillin, piperacillin, mezlocillin and ticarcillin. Also include penicillins mixed with sulbactam or clavulanic acid (e.g., ticarcillin + clavulanic acid = Timentin).	Required field.
11. Quinolones	Enter "1" (Yes) or "2" (No). If Yes, select the antibiotic from the list and enter the corresponding number(s) in the field(s). Examples include ofloxacin, ciprofloxacin.	Required field.
12. Vancomycin	Enter "1" (Yes) or "2" (No).	Required field.
13. Other Antibiotic	Enter "1" (Yes) or "2" (No). Enter yes only if the antibiotic does not belong to the above broad classifications of antibiotics.	Required field.
14. Antipsychotics (e.g. haloperidol, droperidol)	Enter "1" (Yes) or "2" (No).	Required field.
15. Antivirals	Enter "1" (Yes) or "2" (No). Include acyclovir, AZT and other anti-HIV agents, rimantadine, amantadine, and CMV immune globulin.	Required field.
16. Experimental therapies	Enter "1" (Yes) or "2" (No). If Yes, select the therapy from the list and enter the corresponding number(s) in the field(s).	Required field.
*__Prednisone__ (option 16.10)	Select this option if patient received >15 mg of prednisolone (or its equivalent) on this calendar day; including oral or parenteral routes (dosing is equivalent).	Dose equivalency to 15 mg prednisone are: hydrocortisone 75 mg, methylprednisolone 12 mg, and dexamethasone 2.25mg.
17. Methylxanthines (e.g. theophylline, pentoxifylline or aminophylline)	Enter "1" (Yes) or "2" (No) to if patient has received any methylxanthines on this calendar day.	Required field.

12-LEAD ECG-On Study

Record ECG within one hour after study drug infusion on study days: 1, 7, 21. If the patient achieves 48 hours of Unassisted Breathing before Day 20, discontinue LSF study drug, and perform the next scheduled ECG.

Heart Rate:	Enter the VENTRICULAR rate in beats per minute.	Required field.
CARDIAC CYCLE MEASUREMENTS:		
P-R interval	Enter time in seconds.	Required field.
QRS interval	Enter time in seconds.	Required field.
Q-T interval	Use absolute Q-T, in seconds (not corrected Q-T).	Required field.
Interpretation:	Enter "1" =Within normal limits, "2"=Abnormal	Required field. "." not acceptable.

DRUG DOSING-ON STUDY

Complete on study days 1,2,4-20 or until drug is discontinued.

IF A PATIENT DEVELOPS A CREATININE LEVEL >2.5 OR A BILIRUBIN LEVEL >3.0, ADDITIONAL STUDY DRUG LEVELS ARE REQUIRED PRE AND POST STUDY DRUG INFUSION, DAILY FOR 3 DAYS AND THEN WEEKLY UNTIL STUDY DRUG DISCONTINUATION.

***REMEBER STUDY DRUG LEVELS AND SURROGATE MARKERS ARE REQUIRED ON DAY 3 FOR ALL PATIENTS.**

1a. Start time:	Enter actual time the infusion started (military).	Required field.
1b. Dosage:	Enter dose in milligrams.	Required field.
2a. Start time:	Enter actual time the infusion started (military).	Required field.
2b. Dosage:	Enter dose in milligrams.	Required field.
3a. Start time:	Enter actual time the infusion started (military).	Required field.
3b. Dosage:	Enter dose in milligrams.	Required field.
4a. Start time:	Enter actual time the infusion started (military).	Required field.
4b. Dosage:	Enter dose in milligrams.	Required field.
5a. Start time:	Enter actual time the infusion started (military). **This field is to be used for instances when a "midnight" dose is actually given prior to 2400, resulting in 5 doses falling on one calendar day.**	Record if available.
5b. Dosage:	Enter fifth dose in milligrams.	Record if available.
6. Study drug levels required?	Additional study drug levels are required: if a patient's creatinine level is >2.5 or bilirubin level is >3.0, DAILY X3 DAYS THEN WEEKLY UNTIL DAY 28 OR HOSPITAL DISCHARGE.	Required field, "." Not acceptable.
7a. Pre-infusion blood draw done?	Enter "1" (yes) or "2" (no).	Required field only if 6 = "1" (yes).
7b. If yes, enter time.	Enter time (military) of blood draw.	Required field if 7a. = "1" (yes).
7c. Enter specimen bar code:	Enter the 8 digit specimen bar code.	Required field if 7a. = "1" (yes).
8a. Post-infusion blood draw done?	Enter "1" (yes), or "2" (no).	Required field only if 6 = "1" (yes).
8b. If yes, enter time:	Enter time (military) of blood draw.	Required field if 8a = "1" (yes).
8c. Enter specimen bar code:	Enter the 8 digit specimen bar code.	Required field if 8a. = "1".
8d. Stop time of infusion:	Enter time (military) that infusion was completed.	Required field only if 6 = "1" (yes).

DRUG DOSING/ SPECIMEN LOG-DAY 3

Complete this form on DAY 3 ONLY.

IF A PATIENT DEVELOPS A CREATININE LEVEL >2.5 OR A BILIRUBIN LEVEL >3.0, ADDITIONAL STUDY DRUG LEVELS ARE REQUIRED PRE AND POST STUDY DRUG INFUSION, DAILY FOR 3 DAYS AND THEN WEEKLY UNTIL STUDY DRUG DISCONTINUATION.

1a. Start time:	Enter actual time the infusion started (military).	Required field.
1b. Dosage:	Enter dose in milligrams.	Required field.
2a. Start time:	Enter actual time the infusion started (military).	Required field.
2b. Dosage:	Enter dose in milligrams.	Required field.
3a. Start time:	Enter actual time the infusion started (military).	Required field.
3b. Dosage:	Enter dose in milligrams.	Required field.
4a. Start time:	Enter actual time the infusion started (military).	Required field.
4b. Dosage:	Enter dose in milligrams.	Required field.
5a. Start time:	Enter actual time the infusion started (military). **This field is to be used for instances when a "midnight" dose is actually given prior to 2400, resulting in 5 doses falling on one calendar day.**	Record if available.
5b. Dosage:	Enter dose in milligrams.	Record if available.
DRUG LEVELS:	LSF STUDY DRUG LEVELS SHOULD BE DRAWN WITHIN **30 MINUTES BEFORE** AND WITHIN **ONE MINUTE AFTER** COMPLETION OF ANY DOSE ON THIS CALENDAR DATE. (REFER TO DAY 0 SPECIMEN HANDLING INSTRUCTIONS).	
6a. Pre-infusion blood draw done?	Enter "1" (yes) or "2" (no).	Required field.
6b. If yes, enter time.	Enter time (military) of blood draw.	Required field if 6a. = "1" (yes).
7a. . Post-infusion blood draw done?	Enter "1" (yes), or "2" (no).	Required field.
7b If yes, enter time:	Enter time (military) of blood draw.	Required field if 7a = "1" (yes).
7c. Stop time of infusion:	Enter time (military) that infusion was completed.	Required field.

DRUG DOSING/SPECIMEN LOG-DAY 3
(Continuation)

SURROGATE MARKERS:	BLOOD SPECIMENS FOR SURROGATE MARKERS SHOULD BE DRAWN WITHIN **30 MINUTES BEFORE** AND **ONE HOUR AFTER** THE COMPLETION OF ANY STUDY DRUG INFUSION ON THIS CALENDAR DATE: 1) Collect two 10.0 ml blood samples, 1 in a 10 ml green top vacutainer tube (sodium heparin) and 1 in a 10 ml red top tube. 2) Place the samples immediately on ice and process WITHIN 2 HOURS OF COLLECTION. 3) Plasma (green top) should be prepared by centrifugation and aliquoted evenly into **four** 1.5 ml polypropylene tubes and should be stored in a freezer set to -20° C. 4) Serum (red top) should also be prepared by centrifugation and evenly aliquoted into **four** 1.5 ml polypropylene tubes and stored in a freezer set to -20° C.	
8a. Pre-infusion blood draw done?	Enter "1" (yes), or "2" (no).	Required field.
8b. If yes, give time.	Enter time (military) of blood draw.	Required field, if 8a = "1" (yes).
9a. Post infusion draw done?	Enter "1" (yes), or "2" (no).	Required field.
9b. If yes, give time.	Enter time (military) of blood draw. BLOOD DRAW IS DUE **1 HOUR AFTER** THE COMPLETION OF STUDY DRUG INFUSION.	Required field, if 9a = "1" (yes).
9c. Stop time of infusion:	Enter time (military) that infusion was completed.	Required field.

FOR DAY 3 CYTOKINES, SEE SPECIMEN COLLECTION FORM IN THE ALL MENU

WEANING
STUDY DAYS: 1-28

Complete this form on all patients on study days 1 through 28 or until the patient achieves 48 hours unassisted breathing or dies, whichever comes first. Use information from the calendar date (midnight-midnight) shown on the computer screen.

ITEM	DEFINITION	DATA RULES
1. Was the patient permanently withdrawn from the ventilator arm of the protocol?	Enter "1" (Yes) or "2" (No) to indicate whether the patient was permanently withdrawn from the ventilator arm of the protocol.	Required field. "." not acceptable.
2. Was the patient permanently withdrawn from the lisofylline/placebo arm of the protocol?	Enter "1" (Yes) or "2" (No) to indicate whether the patient was permanently withdrawn from the Lisofylline/placebo arm of the protocol.	Required field. "." not acceptable.
3. At 0600 the patient was on:	Indicate the ventilator mode at 0600. Enter "1" if the patient was on Volume Assist/Control or "2" if the patient was on Pressure Support. Enter "3" if the patient was on Unassisted Breathing.	Required field. "." not acceptable. If answer = "2", go to Weaning History, #5 a-h. If answer = "3", go to #6.
4. Did patient meet weaning evaluation criteria?	(a) $\geq$ 12 hours since initial protocol ventilator changes, if any. (b) $FiO_2 \leq .40$. (c) Values of both PEEP and $FiO_2 \leq$ values from the previous day (comparing reference measurement values). (d) Not receiving neuromuscular blocking agents, and without neuromuscular blockade. (e) Patient exhibiting inspiratory efforts (ventilator rate should be decreased to 50% of baseline level for up to 5 minutes to detect inspiratory efforts if no efforts are evident at baseline ventilator rate. (f) Systolic BP $\geq$ 90 mm Hg without vasopressor support.	Required field. "." not acceptable. If answer = "2" or "3", go to #8, "Was pt on A/C continuously...?"
4a. If 4 is Yes, did the patient pass the 5 min. CPAP trial?	Enter "1" if a 5-minute CPAP trial was conducted and the patient's respiratory rate remained $\leq$ 35 breaths/min. Enter "2" if RR > 35 during the CPAP trial. Enter "3" if the CPAP trial was not conducted.	Required field if #4 ="1" (Yes) If answer = "2" (No), go to #8, "was pt on A/C continuously...?"

WEANING
(Continuation)

5. Were there attempts to wean PS by 5 cm H_2O?	Enter "1" (Yes), "2" (No), or "3" (Not tried) to indicate if the patient tolerated reductions in Pressure Support to 5 cmH_2O. The criteria for tolerance are in Section 5.1.2.3 of the ARDSnet Study 01.	Required field if #4 ="1" (Yes) If answer = "2" (No), go to #8, "Was pt on A/C continuously..?".
5a-h. Weaning History	Record initial and subsequent pressure support levels along with their corresponding starting times (military) each time the Pressure Support Level is changed.	Required field if #5 ="1" (Yes)
6. Did patient tolerate of trial of spontaneous breathing > 2 hours?	Enter "1" (Yes), "2" (No), or "3" (Not tried) to indicate if the patient tolerated a trial of spontaneous breathing > 2 hrs.	Required field. "." not acceptable.
7. Did patient complete 48 hours of unassisted breathing?	Enter "1" (Yes) or "2" (No) to indicate if patient **COMPLETED** 48 hours of "Unassisted Breathing" on this calendar date (the **START** date is captured on the Study Termination form). See section 5.1.2.6 of the ARDSnet Study 01 for definition of "Unassisted Breathing".	Required field. "." not acceptable.
RANDOM VENTILATOR CHECK	FOR ITEMS 8-12 ENTER FIRST VALUE IN FOUR HOUR INTERVAL **ON OR AFTER** THE VENTILATOR CHECK	
8. Was patient on A/C continuously during 4 hrs preceding and 4 hrs following selected vent check time?	Enter "1" (Yes), or "2" (No).	
9. FiO_2	Enter the FiO_2 as a decimal (e.g. .50).	Required field. "." not acceptable.
10a. Calculated delivered tidal volume (if on A/C)	Enter the inspired tidal volume (ml) set on the ventilator minus any additional tidal volume added to correct for gas compression and ventilator tube expansion (this should = the tidal volume called for by the protocol; this will not = the volume set on the ventilator unless the ventilator makes automatic adjustments for gas compression/tube expansion). Puritan-Bennett 7200's and some other ventilators make this correction automatically, in which case the tidal volume set on the ventilator should = the tidal volume called for in the protocol. For patients on these ventilators, enter the tidal volume set on the ventilator.	Required field. "." not acceptable.

WEANING
(Continuation)

10b. Was tidal volume increased because of severe dyspnea?	Enter "1" (yes) if tidal volume was increased because of the conditions described in 5.1.1.2.biii (protocol, pg. 26).	Required field, "." not acceptable.
11. PEEP	Enter the level of PEEP in cmH_2O.	Required field, "." not acceptable.
12. Set Rate	Enter the minimum respiratory rate set on the ventilator (not the actual rate, which may exceed the set rate).	Required field, "." not acceptable.
13. Pplat Mid	Enter the middle of the three values of plateau pressure measured.	Required field, "." not acceptable.
RANDOM VENTILATOR CHECK	FOR ITEMS 14-16 ENTER THE LAST VALUE IN THE FOUR HOUR INTERVAL **PRIOR TO** (BUT NOT ON) THE RANDOM VENTILATOR CHECK TIME	
14a. pH	Enter the most recent value during the four hour interval **PRIOR** to the random ventilator check, if available. If not available, enter "."	Required field.
14b. If pH available, was set rate changed in the 4 hr interval between measurement and time set rate recorded?	Enter "1" (yes) or "2" (no).	Required field.
15a. SpO_2 (enter corrected SpO_2 if adjusted using SaO_2)	If SpO2 was used to set or assess PEEP and FiO2 (items 9 and 11) enter the most recent pulse oximetry value PIROR to the time of the random ventilator check.	Required field.
15b. If SpO_2 was used was FiO_2 or PEEP changed in the interval between SpO_2 measurement and time FiO_2 or PEEP recorded? (items 9 and 11)	Enter "1" (yes) or "2" (no).	Required field.
16a. PaO_2	Enter the most recent value PRIOR to the randomly selected ventilator check time, in mm Hg. If both SpO2 and PaO2 are available, and if **SpO2** was used to assess FiO2 and PEEP (in items 9 and 11) enter "." and skip to item 17.	Required field.
16b. If PaO_2 was used, was FiO_2 or PEEP changed in the interval between PaO_2 measurement and the time FiO_2 or PEEP recorded? (items 9 and 11).	Enter "1" (yes) or "2" (no).	Required field.

17. If no pH available for question 14a, then enter most recent.	If no pH available in the 4 hour interval prior to random vent check but was available on this calendar date, enter most recent. If unavailable enter ".".	Required field.

GLASGOW COMA SCORE
Study Days: 7, 14, 21, 28

Complete this form on the 7th, 14th, 21st, 28th study day. Use the worst values for the date.

ITEM	DEFINITION	DATA RULES
Glasgow Coma Score (GCS)	Use the worksheet provided to calculate the worst GCS for this calendar date. All three components should originate from the same time point.	Required field. "." not acceptable.
1. Eye Opening Score	Enter a value (1,2,3, or 4) to indicate best response. If patient's eyes are swollen shut, estimate best response.	Required field. "." not acceptable
2. Motor Response Score	Enter a value (1,2,3,4,5, or 6) to indicate best response.	Required field. "." not acceptable
3. Verbal Response Score	Enter a value (1,2,3,4, or 5) to indicate best response. If patient was intubated for 24 hours prior to initial study procedures, use clinical judgment to estimate best response. If unsure, enter "3".	Required field. "." not acceptable
4. GCS (total)	Computer calculated total Glasgow Coma Score.	Calculated value

BRUSSELS TABLE
STUDY DAYS: 1-28

Complete this form using available data on each study day through Day 28 or until death or discharge, whichever comes first.

In the row labeled "Day 0.5", enter data pertaining to the date of enrollment from the time immediately following initial study procedures until 2359.59 (11:59.59 pm).

In the rows for Days 1-28, enter data from the first through the 28th calendar date after the date of enrollment. Each of these calendar dates includes the interval from 0000 (Midnight) until 23:59.59.

Record the worst values for each of the five variables shown at the headings of the columns. If a variable was not measured on a calendar date, enter "."

Worst values are defined below:

Systolic	**Lowest** value for the date.
P/F Ratio	**Lowest** value for the date.
Platelets	**Lowest** value for the date.
Creatinine	**Highest** value for the date.
Total Bilirubin	**Highest** value for the date.

Vasopressors yes/no: Enter "1" to indicate that one or more vasopressors were used on the calendar date. Enter "2" if no vasopressors were used on the calendar date. "Vasopressor" is defined as: Dopamine $\geq$ 6 mcg/kg/min and Neo-Synephrine, epinephrine, or Levophed at any rate. Dobutamine is NOT considered a vasopressor. Vasopressors is required all days that patient is in study.

Systolic BP is required except for Day 0.5.

ADVERSE EVENT

This form should be used to capture the following events:

- Adverse Events specified by the protocol:
  - **Increased intracranial pressure (↑ ICP)**: (> 20 mm Hg, if measured)
  - **GI bleed**: (frank blood or "coffee ground" drainage per NG tube)
  - **Arrhythmias**: (Episodes of ventricular tachycardia, sustained or unsustained ventricular fibrillation, supraventricular tachycardia other than sinus tachycardia but including atrial fibrillation/flutter, complete heart block or high-grade A-V block, and sinus bradycardias with rate < 50/min.) (Potential complications of hypercapnia)
  - **Nausea and/or Vomiting** (Potential Complications of Lisofylline).
- Serious, Unexpected and Drug Related Adverse Events
- Other Adverse Events Not Systematically captured by the protocol. This includes Fatal Adverse events and Unexpected Deaths.
- **All hospital readmissions to study day 60 for Serious Adverse Events.**

The Adverse Event Form should not be used to report organ failure related to ARDS or the patient's underlying condition as these events are systematically captured by the protocol.

The Adverse Event Report Form is no longer being used as a death report form. A separate Death Report Form in the ALL menu is to be used to record all death occurring during the study hospitalization to Day 180, and ALL deaths, regardless of location, to Day 60.

ALL SERIOUS AND UNEXPECTED ADVERSE EVENTS SHOULD BE REPORTED TO THE CLINICAL COORDINATING CENTER WITHIN 24 HOURS BY PHONE REGARDLESS OF THEIR RELATIONSHIP TO STUDY DRUG. The investigator must submit a detailed, written report to the Clinical Coordinating Center within 5 working days. A printed copy of this form including a narrative description of the AE under item 4 may be sufficient. The Institutional Review Board should be notified based on institutional policy, but no later than 5 working days after the event is discovered.

ITEM	DEFINITION	DATA RULES
1. Date of event:	Enter the date the event first occurred	Required field.
2. Time of event:	Enter the time the event began	Required field.
3. Specified event:	Enter the corresponding number for the identified event for items 1-5. (Note that there is no #4).	Required field.
4. Describe event or problem:	Give a brief narrative description of problem. If death, give primary cause.	Required field.

ADVERSE EVENT
(Continuation)

5. Severity of event:	Select one: **miid**-Any event that is usually transient, requires no special treatment and does not interfere with the patient's daily activities. **moderate**- Any event that introduces a low level of inconvenience or concern to the patient and may interfere with daily activities. Usually ameliorated by simple measures. **severe**- Any event that if fatal or immediately life threatening, is permanently disabling, or severely incapacitating, or requires or prolongs inpatient hospitalization	Required field.
6. Therapeutic intervention?	Answer "1" (Yes) or "2" (No)	Required field.
7. Immediate risk of death?	Answer "1" (Yes) or "2" (No)	Required field.
8. Death related to event?	Answer "1" (Yes) or "2" (No)	Required field.
9. Unexpected or more severe?	Answer "1" (Yes), "2" (No) or "3" (Unknown). **Unexpected or more severe**- Any experience not identified by type, severity, or frequency in the current study protocol or clinical safety updates or an event unexpected in ARDS or more severe or frequent than expected in ARDS	Required field.

ADVERSE EVENT
(Continuation)

10. Causal relationship to study drug?	Select the answer which best describes the event's relationship to the study drug. **1=Definitely Associated**- The event follows: 1) A reasonable, temporal sequence from drug administration. 2) Cannot be explained by the known characteristics of the patient's clinical state or other therapies. 3) Evaluation of the patients clinical state indicates to the investigator that the experience is definitely related to the study drug. **2=Probably or 3=Possibly Associated:** The event should be assessed following the same criteria for "Definitely Associated". If in the investigator's opinion at least one or more of the criteria are not present, then "probably" or "possibly" associated should be selected. **4=Probably Not Associated:** The event occurred while the patient was on the study but can reasonably be explained by the known characteristics of the patients clinical state or other therapies. **5=Definitely Not Associated:** The event is definitely produced by the patient's clinical state or by other modes of therapy administered to the patient. **6=Uncertain Association:** The event does not meet any of the criteria previously outlined.	Required field.
11. Study drug discontinued?	Answer "1"(Yes) or "2"(No) if the study drug was discontinued related to this event. COMPLETE AN **EARLY DRUG DISCONTINUATION FORM** IF THE AE RESULTED IN PREMATURE WITHDRAWAL OF LSF STUDY DRUG.	Required field.
12. Withdrawn from ventilator study?	Answer "1"(Yes) or "2"(No) if the patient was withdrawn from the ventilator study because of this event.	Required field.
13. Outcome of the EVENT to date	Ongoing assessment. The final answer should be reflective of the status of the EVENT (not the patient) at death, discharge, or study day 28 (whichever comes first). If the answer selected is "1"(recovered), list the date of recovery from the event.	Required field.

DEATH REPORT

This form should be used to capture ALL patient deaths that occur during study hospitalization to Day 180 and all deaths, regardless of location, to Day 60. This replaces the death report option from the previous ARDSnet Study 01 Adverse Event Form. ALL UNEXPECTED DEATHS TO DAY 60 ARE TO BE REPORTED TO THE CCC IMMEDIATELY.

ITEM	DEFINITION	DATA RULES
1. Date of Death:	Enter the date (mm/dd/yy) that the patient died.	Required field.
2. Cause of Death:	List PRIMARY cause of death, ie., respiratory failure, septic shock, renal failure.	Required field.
RELATIONSHIP OF INFECTION TO DEATHS OCCURRING IN THE FIRST 28 DAYS:	FOR ARDSnet STUDY 03, INVESTIGATORS ARE REQUIRED TO DETERMINE THE RELATIONSHIP OF INFECTION TO DEATH FOR ALL DEATHS OCCURRING UP TO AND INCLUDING STUDY DAY 28.	
2a. If patient died within 28 days, was death related to infection?	Enter "1" (not related), "2" (possibly related), or "3" (probably related) to indicate if patient's death was as a result of an infection. (Refer to section 7.2.5 of ARDSnet Study 03 for definition of infection related death.) Enter "4" (not applicable) if death occurred after Study Day 28.	Required field.
3. Describe event:	Give a brief narrative of the cause of death including body system involved, i.e., "respiratory failure secondary to pulmonary hemorrhage" . If support was withdrawn, please describe the clinical course following withdrawal, i.e., family requests withdrawal of ventilator, comfort measures instituted and patient died of respiratory failure.	Required field.

SPECIMEN COLLECTION
Study Days: 0,1, and 3

Collect blood samples for cytokines on Study Days: 0, 1, and 3. Cytokines samples are IN ADDITION to LSF Study Drug levels and Surrogate Markers.

The Specimen Collection Form is located in the ALL menu.

Day 0 blood for cytokine	Enter "1" (yes) or "2" (no) and enter the date (mm/dd/yy) to indicate if blood was drawn this calendar day for cytokines.	Required field.
Day 1 blood for cytokine	Enter "1" (yes) or "2" (no) and enter the date (mm/dd/yy) to indicate if blood was drawn this calendar day for cytokines.	Required field.
Day 3 blood for cytokine	Enter "1" (yes) or "2" (no) and enter the date (mm/dd/yy) to indicate if blood was drawn this calendar day for cytokines.	Required field.
BLOOD CYTOKINES	Collect plasma for blood cytokines **only on Day 0,1 and 3:** 1. Draw blood from patient via arterial line, venous line, or by venipuncture. Use at least an 18 gauge needle for venipuncture and when instilling blood into the purple top Vacutainer to prevent hemolysis of the specimen. Hemolyzed samples should be redrawn if possible. 2. Gently invert the Vacutainer 2-3 times to mix. 3. Place on ice if unable to centrifuge immediately. 4. Centrifuge for 10 minutes at approximately 1500-3000 rpm (standard table-top centrifuge may be used). 5. Withdraw plasma (do not remove buffy coat) using a pipette or syringe and fill purple top micro tubes (2 ML OF PLASMA IN EACH OF 3 TUBES) with plasma. 6. Attach appropriate bar-coded label which contains an ID number and contents of tube. 7. Place on ice until able to freeze at -70° C (ASAP). 8. Comment on any deviation from protocol, such as late sampling or hemolyzed samples.	

BACTEREMIA

This form should be used to document the presence of bacteremia due to known pathogen with or without signs or symptoms. All positive blood cultures of a known pathogen should be recorded. If two bottles are inoculated with a single blood draw, then this counts as one blood culture. If only one of the two bottles grows a known pathogen, then include this blood culture as a positive blood culture.

If criteria are met for a primary site of infection and for bacteremia during the same 48 hour time period, e.g., nosocomial pneumonia/bacteremia or empyema/bacteremia, then the combination will be counted as one event of serious infection and not as two separate events. THE PRIMARY SITE OF INFECTION WILL BE RECORDED AS THE SERIOUS INFECTION, NOT THE BACTEREMIA.

ITEM	DEFINITION	DATA RULES
1 through 20	Enter the date and time of each blood culture obtained that was positive for bacteremia. Select the organism identified from this culture and enter the corresponding number in this field.	

SEPSIS

Complete this form for EACH EPISODE of septic shock. An episode resolves when systolic BP is ≥ 90 mmHg and the patient is off pressors for 1 calendar day. SBP may transiently (≤ 2 consecutive hours) fall below 90 mmHg or pressors may be used transiently (≤ 2 consecutive hours).

ITEM	DEFINITION	DATA RULES
1a. Were two or more of the following SIRS criteria present?	Enter "1" (Yes) if two or more of the listed SIRS criteria are present or "2" (No) if they are not present.	Required field.
1b. If Yes, date of SIRS onset	Enter the date of the onset of SIRS criteria.	Required only if answer to 1a is "Yes".
2a.-2c.	One or more of the following shock criteria must be present for ≥ 2 consecutive hours despite fluid resuscitation to meet septic shock criteria. Select all that apply.	Required fields.
2a. Systolic BP < 90mmHg?	Enter "1" (Yes) or "2" (No).	Required field.
2b. Reduction ≥ 40mmHg from baseline?	Enter "1" (Yes) or "2" (No).	Required field.
2c. Pressor requirement to maintain BP?	Enter "1" (Yes) or "2" (No). Vasopressor is defined as dopamine ≥ 6 mcg/Kg/min, Neo-Synephrine, epinephrine, or Levophed at any rate.	Required field.
2d. Date first shock criteria met	Enter the date in which the first criteria for septic shock was met.	Required field.
3. Primary site of infection identified?	Enter "1" (Yes) or "2" (No). If Yes, select the site from the list and enter the corresponding number(s) in the field(s).	Required fields.
4a. Did shock resolve?	Enter "1" (Yes) or "2" (No). Resolution is defined as systolic BP ≥ 90mmHg AND off pressors for 1 calendar day. SBP may transiently (≤ 2 consecutive hours) fall below 90mmHg or pressors may be used transiently (≤ 2 consecutive hours) on this calendar day.	Required field.
4b. If Yes, date of resolution	Enter the date in which this episode of septic shock was resolved.	Required field.

PNEUMONIA

Complete this form when pneumonia is present. If septic shock developed as a consequence of this infection, fill out a septic shock form (if not already done).

ITEM	DEFINITION	DATA RULES
1. Date of diagnosis	Enter the date in which the diagnosis of pneumonia was made.	Required field.
2a. Chest radiograph shows new infiltrate that has persisted for 48 hours.	Enter "1" (Yes) if condition is met within a 48 hour period. Other-wise enter "2" (No).	Required field.
2b. New fever or hypothermia or leukocytosis or leukopenia	Enter "1" (Yes) if condition is met within a 48 hour period. Other-wise enter "2" (No).	Required field.
3. Was an endotracheal aspirate sent for gram stain?	Enter "1" (Yes) or "2" (No).	Required field.
4. Was an endotracheal aspirate sent for culture?	Enter "1" (Yes) or "2" (No).	Required field.
5a. Was there bacteriologic confirmation of this episode of suspected pneumonia?	Enter "1" (Yes) or "2" (No). Bacteriologic confirmation is defined in Appendix A.4.c.iii.	Required field.
5b. Organism 1	Select the organism identified in greatest number and enter the corresponding number in this field.	If entry = ".", then this form is complete.
5c. Organism 2	Select the organism identified in the second greatest number and enter the corresponding number in this field.	If entry = ".", then this form is complete.
5d. Organism 3	Select the organism identified in the third greatest number and enter the corresponding number in this field.	If entry = ".", then this form is complete.

FUNGAL INFECTION

Complete this form when a fungal form is present. If septic shock developed as a consequence of this infection, fill out a septic shock form (if not already done).

ITEM	DEFINITION	DATA RULES
1a. Blood culture positive for yeast infection?	Enter "1" (Yes) or "2" (No).	Required field.
1b. If Yes, date	If the blood culture is positive for yeast infection, enter the date of the culture.	Required field.
2a. Evidence of deep tissue infection (endophthalmitis, hepatic/splenic abscesses/cutaneous emboli with fungal elements)?	Enter "1" (Yes) or "2" (No).	Required field.
2b. If Yes, date of diagnosis	If there is evidence of deep tissue infection, enter the date of this diagnosis.	Required field.
3a. Unexplained fever with three sites of colonization?	Enter "1" (Yes) or "2" (No).	Required field.
3b. If yes, date of diagnosis	If there is an unexplained fever with three sites of colonization, enter the date of this diagnosis.	Required field.
4a. Oral or mucosal candidiasis?	Enter "1" (Yes) or "2" (No).	Required field.
4b. If Yes, date of diagnosis	If there is oral or mucosal candidiasis, enter the date of this diagnosis.	Required field.
5. Organism	Select the organism identified and enter the corresponding number in this field.	Required field.

PERITONITIS

This form is to be used 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.

If septic shock developed as a consequence of this infection, fill out a septic shock form (if not already done). If blood cultures positive, fill out bacteremia form.

ITEM	DEFINITION	DATA RULES
1. Date of diagnosis	Enter the date of diagnosis of peritonitis.	Required field.
2. Peritoneal Fluid Cultures	Select the organism identified from the cultures and enter the corresponding number in this field.	Required field.

WOUND INFECTION

This form is to be used for wound infection requiring extensive debridement and/or healing by secondary intention.

If septic shock developed as a consequence of this infection, fill out a septic shock form (if not already done). If blood culture positive, fill out bacteremia form.

ITEM	DEFINITION	DATA RULES
1. Date of diagnosis	Enter the date of diagnosis of the wound infection.	Required field.
2. Wound culture	Select the organism identified from the culture and enter the corresponding number in this field.	Required field.

VIRAL INFECTION

This form is to be used for disseminated viral infections. If septic shock developed as a consequence of this infection, fill out a septic shock form (if not already done).

ITEM	DEFINITION	DATA RULES
1. Date of diagnosis	Enter the date of diagnosis of the viral infection.	Required field.
2. Organism	Select the organism identified and enter the corresponding number in this field.	Required field.

MENINGITIS

Complete this form when pneumonia is present. If septic shock developed as a consequence of this infection, fill out a septic shock form (if not already done). If blood cultures positive, fill out bacteremia form.

ITEM	DEFINITION	DATA RULES
1. Date of diagnosis	Enter the date of diagnosis of meningitis.	Required field.
2. Organism recovered from cerebrospinal fluid	Select the organism identified and enter the corresponding number in this field.	Required field.

EMPYEMA

Complete this form when empyema is present. If septic shock developed as a consequence of this infection, fill out a septic shock form (if not already done). If blood cultures positive, fill out bacteremia form.

ITEM	DEFINITION	DATA RULES
1. Date of diagnosis	Enter the date of diagnosis of empyema.	Required field.
2. Organism	Select the organism identified and enter the corresponding number in this field.	Required field.

DEEP TISSUE ABSCESS

This form is to be used for abdominal or other deep tissue abscess. If septic shock developed as a consequence of this infection, fill out a septic shock form (if not already done). If blood cultures positive, fill out bacteremia form.

ITEM	DEFINITION	DATA RULES
1. Date of diagnosis	Enter the date of diagnosis of the deep tissue abscess.	Required field.
2. Organism	Select the organism identified and enter the corresponding number in this field.	Required field.
3. Site of infection/abscess	Select the site identified and enter the corresponding number in this field.	Required field.

OTHER INFECTION

This form is to be used for infections other than those for which other forms exist. If septic shock developed as a consequence of this infection, fill out a septic shock form. If blood cultures positive, fill out bacteremia form.

ITEM	DEFINITION	DATA RULES
1a. C. difficile colitis?	Enter "1" (Yes) or "2" (No).	Required field.
1b. If Yes, give date	Enter the date of diagnosis of C. difficile colitis.	Required field.
2a. Indwelling vascular line infection?	Enter "1" (Yes) or "2" (No).	Required field.
2b. If Yes, give date	Enter the date of the line infection.	Required field.
3a. Peritonitis (on Peritoneal Dialysis)?	Enter "1" (Yes) or "2" (No).	Required field.
3b. If Yes, give date	Enter the date of peritonitis.	Required field.
4a. Sinus infection?	Enter "1" (Yes) or "2" (No).	Required field.
4b. If Yes, give date	Enter the date of sinus infection.	Required field.
5a. Skin infection?	Enter "1" (Yes) or "2" (No).	Required field.
5b. If Yes, give date	Enter the date of skin infection.	Required field.
6a. Septic arthritis?	Enter "1" (Yes) or "2" (No).	Required field.
6b. If Yes, give date	Enter the date of septic arthritis.	Required field.
7a. Urinary Tract Infection?	Enter "1" (Yes) or "2" (No).	Required field.
7b. If Yes, give date.	Enter the date of urinary infection.	Required field.
7a. Other infection	Enter "1" (Yes) or "2" (No). Enter the name of the identified infection.	Required field.
7b. If Yes, give date	Enter the date of other infection.	Required field.

EARLY DRUG DISCONTINUATION

Complete this form if the patient was prematurely withdrawn from the LSF Study Drug Arm of the protocol.

Premature withdrawal means that LSF Study Drug was discontinued prior to the completion of 48 hours of Unassisted Breathing OR Day 20, whichever occurs first.

ITEM	DEFINITION	DATA RULES
Reason(s) for discontinuation?	Enter, from the pick list, the reason that the patient was withdrawn from the Lisofylline Study Drug Arm of the protocol.	First field is required, 2nd and 3rd use if applicable.
Pick list:		
1. Unacceptable toxicity.		
2. Withdrawal of patient/surrogate consent.		
3. Unforeseen events:	For example, newly diagnosed malignancy or vasculitis requiring specific treatment.	
4. MD withdraws patient.		
5. Death:	Complete adverse event report (if appropriate) and a death report.	
6. Adverse Event::	Complete adverse event report.	
7. Protocol Violation.		
8. Other:	Give brief description of reason.	

STUDY TERMINATION

Complete this form on each patient enrolled in ARDSnet Studies 01 and 03 on study Day 28 and study Day 60 (Day of Enrollment is study Day 0).

If a patient was discharged before Day 28 or Day 60, telephone follow-up is required to determine status at Day 28 AND Day 60.

If a patient is alive after Day 60 but is not discharged home with Unassisted Breathing, check on patient status at intervals of ≤ 30 days until:

1. **The patient goes home with unassisted breathing, OR**
2. **The patient dies, OR**
3. **Until Study Day 180, whichever comes first.**

ITEM	DEFINITION	DATA RULES
1. Patient Status	Enter "1" if the patient went home with unassisted breathing. Enter "2" if the patient died prior to discharge home with unassisted breathing or died prior to achieving unassisted breathing at home for 48 hours. Enter "3" if neither condition "1" nor condition "2" applies. E.g., if the patient went home on assisted breathing and has not achieved unassisted breathing for 48 hours. continues on assisted breathing. (a "3" status requires follow-up every 30 days).	Required field. "." not acceptable.
1a,b,c. Dates	Enter date of discharge home with unassisted breathing (if condition 1 above), date of death prior to discharge home with unassisted breathing (if condition 2, above), or of last patient contact (if condition 3 above).	Required field. "." not acceptable.
2. Was the patient able to sustain unassisted breathing for ≥ 48 hours during the first 28 days after initiation of study procedures?	Enter "1" (Yes) or "2" (No). "First 28 days" indicates the period from Day 0 through Study Day 28.	Required field. "." not acceptable.
2a. Date of **beginning** of unassisted breathing during first 28 days if sustained for ≥ 48 hours.	Enter the **START** date of the first period of unassisted breathing that lasted for ≥ 48 hours (the **end** date is captured on the weaning form).	Required field if #2 = "1" (Yes) "." not acceptable.

STUDY TERMINATION
(Continuation)

3. Did patient return to assisted breathing during the first 28 days (if answer to #2 above is "Yes").	Enter "1" (Yes) or "2" (No). **A PATIENT REQUIRING ASSISTED BREATHING < 24 HOURS FOR A SURGICAL PROCEDURE NO LONGER COUNTS AS A RETURN TO ASSISTED BREATHING.**	Required field if #2 = "1" (Yes) "." not acceptable.
3a. Enter the number of calendar dates on which the patient required assisted breathing between the date in 2a and Day 28.	If the patient achieved 48 hours of unassisted breathing but returned to assisted breathing before day 28, enter the number of calendar dates on which the patient was on assisted breathing from midnight to midnight. *Do not count periods of assisted breathing lasting < 24 hours for a surgical procedure.*	Required field. "." not acceptable.
3b. If 3 = yes, was the patient able to sustain another period of unassisted breathing for ≥ 48 hours without returning to assisted breathing by Day 28?	Enter "1" (yes) or "2" (no) to indicate if a patient was able to tolerate 48 hours of Unassisted Breathing that lasted through Day 28. *Do not count periods of assisted breathing lasting < 24 hours for a surgical procedure.*	Required field if 3 = "1" (yes).
3c. If 3b = yes, enter beginning date of the last period of Unassisted Breathing.	Enter the **START** date of the last period of Unassisted Breathing that lasted for ≥ 48 hours and CONTINUED THROUGH DAY 28.	Required field if 3b = "1" (yes).
4. Was the patient discharged alive from ICU during the first 28 days?	Enter "1" (Yes) or "2" (No) to indicate if the patient was discharged alive from an intensive care unit. If the patient was transferred from one intensive care unit to another but died prior to discharge from the subsequent ICU(s), enter "2".	Required field. "." not acceptable.
4a. Date of discharge alive from ICU?	If answer to question 4 above is "Yes", enter the date the patient was discharged alive from ICU. If the patient was discharged alive from ICU more than once during the first 28 days, enter the first date.	Required field if #4 = "1" (Yes). "." not acceptable.
5. Did the patient return to an ICU during the first 28 days?	Enter "1" (Yes) or "2" (No) to indicate if the patient was re-admitted to an ICU during the first 28 days after enrollment.	Required field. "." not acceptable.
5a. Enter the number of calendar dates on which the patient received any ICU-care between the date in "4a" and day 28.	If the answer to question "5" was "Yes" (the patient was discharged alive from ICU prior to day 28 but then was readmitted to an ICU prior to day 28), enter the number of calendar dates on which the patient received any ICU-care.	Required field. "." not acceptable.

STUDY TERMINATION
(Continuation)

6. Was the patient discharged alive from study hospital?	Enter "1" (Yes) or "2" (No).	Required field. "." not acceptable.
6a. Date of discharge from hospital.	Enter date if item 6 is (Yes).	Required field if 6= "1" (yes).
6b. Status at Study Day 28:	Enter "1" (alive) or "2" (dead). If discharged prior to Day 28, telephone follow-up is required.	Required field. "." not acceptable.
7. Status at Study Day 60:	Enter "1" (alive) or "2" (dead). If discharged prior to Day 60, telephone follow-up is required.	Required field. "." not acceptable.
FILL OUT A DEATH REPORT FOR ALL DEATHS. FILL OUT AN ADVERSE EVENT REPORT FOR ALL SERIOUS ADVERS EVENTS (SAEs), REHOSPITALIZATIONS FOR SERIOUS ADVERSE EVENTS, AND ALL UNEXPECTED DEATHS UP TO DAY 60. COMPLETE A DEATH REPORT FOR HOSPITAL DEATHS TO DAY 180; ALL DEATHS TO DAY 60.		