

***NIH ARDS Network
FACTT-ARDSNet Study 05***

Prospective, Randomized, Multi-Center Trial of Pulmonary Artery Catheter (PAC) vs. Central Venous Catheter (CVC) for Management of Acute Lung Injury (ALI) and Acute Respiratory Distress Syndrome (ARDS).

And

Prospective, Randomized, Multi-Center Trial of "Fluid Conservative" vs. "Fluid Liberal" Management of Acute Lung Injury (ALI) and Acute Respiratory Distress Syndrome (ARDS).


CASE REPORT FORM INSTRUCTIONS
VERSION 4
09/18/02

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INTRODUCTION

This manual contains instructions for completing the case report forms on patients enrolled in the ARDS Network study 05-Fluid and Catheter Treatment Trial (FACTT).

- 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.
- A  symbol indicates instructions specific to using a form in the MetaTrial system.
- **In the MetaTrial CRFs:** for questions with radio buttons, the option “No Answer” indicates that there has been no data entered, i.e., the question is blank.
- **ADDITIONAL COMMENTS:** Comments can be entered on any field in the CRFs in the MetaTrial system. Use this option in place of the previous “additional comment” form to document any additional information regarding a data point. Comments can be entered or viewed by clicking on the “Show Info” button in the Form Toolbar and selecting “Comments” from the pull-down menu.
- Some of the case report form pages must be completed only once on each patient (e.g., “INCLUSION CRITERIA” and “BASELINE VENTILATOR PARAMETERS”). For these pages, the corresponding instruction manual pages will be required only once. Other case report form pages must be completed on several dates after enrollment (e.g., “ON STUDY VITAL SIGNS” AND “WEANING FORM”). For these pages, the corresponding instruction manual pages should be used each time the case report form page is completed.
- 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.
- 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. If there is a data item for which data will *never* be available, right-click on the field with your mouse. Select “missing data” from the pull-down menu. A pop-up window will appear asking to confirm changing field to “missing data” status. Once this is completed, the field will turn yellow. A yellow field will indicate that there is no available data for this item.

FORM: ALI SCREENING


DAYS AVAILABLE: **DAY 0**

INSTRUCTIONS: Complete this form for all patients meeting the study inclusion criteria in regularly screened ICUs and for patients identified in other ICUs. If patient has already been screened for ALVEOLI study, do not enter outcome data on this form.



Inclusion Criteria

Acute onset of:

1. **PaO₂/FiO₂ ≤ 300.** If altitude > 1000m, use (PaO₂/FiO₂) ≤ (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 x 12 hours).

DATA ITEM	DETAILS	LOGIC RULES
1) Acute onset	Select (Yes) or (No). Acute onset is defined as follows: PaO ₂ /FiO ₂ ratio ≤ 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.	Select YES or NO
THE FOLLOWING INCLUSION CRITERIA (2a-c, 3) MUST OCCUR WITHIN A SINGLE 24 HOUR INTERVAL (See protocol pg 11).		
2a) PaO ₂ /FiO ₂ ≤ 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.	Pt must meet all 3 criteria to select YES to item 2. TIME OF QUALIFYING CXR IS REQUIRED FOR ENROLLED PATIENTS ONLY.
2b) Bilateral infiltrates consistent with pulmonary edema? Date/Time of CXR used to answer question 2b.	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.  Select the date (click on the <i>date</i> button to activate the pop-up calendar) and time (military) of the QUALIFYING chest radiograph. Source documentation of qualifying chest film (date and signature of reader) is required.	
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.	
3. No clinical evidence of left atrial hypertension. If measured, pulmonary arterial wedge pressure ≤ 18 mmHg.	Select the option that best applies. Yes =NO evidence of left atrial hypertension; NO = evidence of left atrial hypertension is PRESENT.	Required field.
4. PaO ₂	Enter the PaO ₂ used to calculate the P/F ratio in 2a above	Required field.
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.

ALI SCREENING FORM (CONTINUED)

DATA ITEM	DETAILS	LOGIC RULES
6. Enter the first date that all these criteria exist simultaneously	 Select the first calendar date from the pop-up calendar 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 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.
7. Gender	Select the appropriate option.	Required field.
8. Ethnicity	Select the option that best applies: 1=White, not of Hispanic Origin, 2=Black (African American), not of Hispanic Origin, 3=Hispanic, 4=Asian/Pacific Islander, 5=American Indian/Alaskan Native, 6=Other.	Required field.
9. Age	Enter patient's age in years at last birthday.	Required field.
10. Location	Select the option that indicates patient's current location: MICU, SICU, Cardiac SICU, CCU, Neuro ICU, Burn, Trauma, Cancer Unit, MICU/SICU, Other.	Required field.
11. Regularly Screened ICU	Enter (Yes) if this ICU is screened at least 5 days each week for ARDSNet studies.	Required field.
12a. Reason for exclusion	Select ALL options that apply. Refer to protocol page 11 for definitions of specified exclusion criteria.	Required field.
12 b. If not excluded but not enrolled, explain.	Occasionally patients meet all inclusion criteria and no exclusion criteria but are not enrolled because they improve quickly or die quickly within the 36 hour enrollment window. For these patients, complete this item.	Required field if 12a = not excluded.
13. Lung Injury Category	Select one primary and 0-4 secondary causes of lung injury: Trauma, Aspiration, 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 ALL: primary category = sepsis; secondary category = trauma.	Required field.  For options that do not apply "NONE" must be selected to complete this form.
13a. If lung injury category =sepsis give site.	Select the option that BEST indicates the site of infection if the primary lung injury category entered in 13 is sepsis.	Required if 13= sepsis.
COMPLETE QUESTIONS 14-17 FOR <u>SCREENED PATIENTS ONLY</u>		
14. Patient able to sustain a period of unassisted breathing for 48 hours during the first 60 days?	Select (Yes) or (No) to indicate if patient achieved 48 hours of unassisted breathing anytime during the first 60 days after the date of screening.	If available.

ALI SCREENING FORM (CONTINUED)

DATA ITEM	DETAILS	LOGIC RULES
15a. If yes, enter the START date that the first period of unassisted breathing was achieved that lasted for 48 hours or more.	Select the date from the pop-up calendar that unassisted breathing began.	Required field if 14=YES.
16. Was patient discharged from study hospital during the first 60 days?	Select (Yes) or (No) to indicate if patient was discharged (alive or dead) from the study hospital during the first 60 days following the date of screening.	Required field for screened patients only.
16a. If yes, give discharge date:	Select the date from the pop-up calendar that the patient was discharged.	Required field if 15 =Yes.
17. Status at discharge:	Select (Alive) or (Dead) to indicate the patient's status at time of discharge.	Required field if 15 =Yes.
COMPLETE THE FOLLOWING QUESTION FOR PATIENTS ALSO SCREENED FOR ALVEOLI		
18. ALVEOLI Screening number:	Enter ALVEOLI screening number if patient was screened for both studies.	Required if screened for ALVEOLI.

FORM: ENROLLMENT

DAYS AVAILABLE: **DAY 0**

INSTRUCTIONS: If a patient meets all inclusion criteria and no exclusion criteria AND it has been < 48 hours since all inclusion criteria were first met, she/he is eligible for study enrollment.

DATA ITEM	DETAILS	LOGIC RULES
1. Has informed consent been obtained?	For questions a, b, & c indicate if patient/family consent has been obtained for <i>each</i> of the 4 areas of consent:	
1a. For participation in THE PAC STUDY?	Informed consent must be obtained before any study procedures are initiated. Select YES if informed consent has been obtained. Select NO if informed consent has not been obtained.	Required field.
PATIENT OR SURROGATE CAN REFUSE THEIR CONSENT FOR GENETIC TESTING AND/OR CEA AND STILL PARTICIPATE IN THE FACTT STUDY		
1b. For genetic testing related to ALI/ARDS?	If the patient or surrogate has given consent for genetic testing for ALI/ARDS only, Select YES, otherwise, select NO.	Required fields.
1c. For genetic testing related to future studies?	If the patient or surrogate has given consent for genetic testing not limited to this study, select YES, otherwise, select NO.	
1d. For participation in the Cost Effectiveness Study?	If the patient or surrogate has given consent for participation in the Cost Effectiveness Study select YES, otherwise, select NO.	Required field.
IF PATIENT IS ELIGIBLE AND CONSENT FOR THE STUDY HAS BEEN OBTAINED, PLEASE CALL FOR RANDOMIZATION NUMBER.		
2. Enter randomization number	This is now entered on the subject form.	N/A
3. Patient randomized to:	Select the corresponding treatment assignment given by the CCC IVRS.	Required field.
4. Date and time of RANDOMIZATION	Enter the date and time (military) that the patient was randomized to the study (TIME LISTED ON THE FAX CONFIRMATION SHEET).	Required field.
5. Footnote Version Number:	Enter the number of the footnotes version that is in effect at the time the patient was enrolled.	Required field.

APACHE III

FORM: APACHE III-DEMOGRAPHICS

DAYS AVAILABLE: DAY 0

INSTRUCTIONS: COMPLETE THIS FORM ON ALL PATIENTS ENROLLED INTO THE STUDY.

DATA ITEM	DETAILS	LOGIC RULES
1. Hospital Admission Date	Select the date from the pop-up calendar the patient was admitted to the study hospital.	Required field.
1a. Hospital Admission Type:	Select the appropriate category of hospital admission.	Required field.
2. ICU Admission Date	Select the date from the pop-up calendar of the current ICU admission.	Required field.
3. Time of ICU Admission	Enter the time the patient was admitted to the current ICU.	Required field.
4. Patient Admitted Directly From:	Select the location 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.
4a. Place of residence:	Select best answer for patient's place of residence prior to admission to hospital.	Required field.
5. Is the patient immediately post-operative from elective surgery?	Select the option that best applies.	Required field.
6. ICU Readmit?	During this hospitalization, was the patient in an ICU prior to this current ICU admission? (Yes/No)	Required field.
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.
8a. Chronic Health Information Available?	Select (Yes) or (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. If item 8a = (No), then skip to question 10.
8b. Is the patient on chronic dialysis or peritoneal dialysis?	Select (Yes) or (No) to indicate if the patient required dialysis prior to hospitalization.	Required field only if 8a = (Yes).
9a. AIDS?	Select (Yes) or (No). Enter (No) if HIV positive but without other AIDS criteria.	Required field only if 8a =(Yes).
9b. Leukemia (AML, CML, all lymphocytic leukemia, multiple myeloma)	Select (Yes) or (No).	Required field only if 8a =(Yes).
9c. Non-Hodgkin's Lymphoma	Select (Yes) or (No).	Required field only if 8a =(Yes).
9d. Solid Tumor with metastasis	Select (Yes) or (No).	Required field only if 8a =(Yes).

APACHE III DEMOGRAPHICS (CONTINUED)

DATA ITEM	DETAILS	LOGIC RULES
9e. Immune Suppression	Select (Yes) or (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 = (Yes).
9f. Hepatic Failure	Select (Yes) or (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 =(Yes).
9g. Compensated cirrhosis.	Select "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 = (Yes).
9h. Diabetes Mellitus	Select (Yes) or (No).	Required field only if 8a = (Yes).
9i. Hypertension	Select (Yes) or (No).	Required field only if 8a = (Yes).
9j. Prior myocardial infarction	Select (Yes) or (No).	Required field only if 8a = (Yes).
9k. CHF	Select (Yes) or (No).	Required field only if 8a = (Yes).
9l. Peripheral vascular disease	Select (Yes) or (No).	Required field only if 8a = (Yes).
9m. Prior stroke with sequelae	Select (Yes) or (No).	Required field only if 8a = (Yes).
9n. Dementia	Select (Yes) or (No).	Required field only if 8a = (Yes).
9o. Chronic pulmonary disease	Select (Yes) or (No).	Required field only if 8a = (Yes).
9p. Arthritis	Select (Yes) or (No).	Required field only if 8a = (Yes).
9q. Peptic ulcer disease	Select (Yes) or (No).	Required field only if 8a = (Yes).
10. Vasopressors last 24 hours?	Select (Yes) or (No) to indicate if the pt has received any vasopressors within the last 24 hours prior to initial vent changes.	Required field.
11. Protocol defined ethanol use?	Select (Yes) or (No) to indicate if patient consumes alcohol per protocol definition- <i>NOT CURRENTLY DEFINED.</i>	Required field.

FORM: APACHE III-PHYSIOLOGY

DAY(S) REQUIRED: **DAY 0**

INSTRUCTION: COMPLETE ON DAY 0. ALL DATA SHOULD BE TAKEN FROM THE 24 HOURS PRECEDING **RANDOMIZATION**. 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 RANDOMIZATION, **the lab tests must be obtained (after obtaining pt/surrogate consent) but before initiating study procedures.**

DATA ITEM	DETAILS	LOGIC 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.
2. Systolic BP	Enter the highest and lowest.	Required field.
3. Mean Arterial Pressure	Enter the highest and lowest.	Required field.
4. Heart Rate	Enter the highest and the lowest.	Required field.
5. Respiratory Rate	Enter the highest and the lowest.	Required field.
6a. Was patient ventilated when the lowest respiratory rate occurred?	Select YES or NO.	Required field.
6b. Was patient ventilated when the highest respiratory rate occurred?	Select YES or NO.	Required field.
7. Urine Output 24 hr	Enter the amount of urine output (ml) in the 24 hrs prior to randomization time. E.g., if time of randomization occurs 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). If a large volume of urine was inadvertently spilled or the urine was not measured, mark the field as "missing data". A urine output value of zero indicates that data are available and the patient produced no urine.	Required field.
8 Hematocrit*	Enter highest and lowest values rounded to the nearest whole number (e.g., "35", not ".35"). If only one value is present for 24 hour period, enter this value as both the highest and lowest.	Required field.
9. WBC* (White Blood Cell count).	Enter highest and lowest as "00000" (e.g., a WBC of 14.2 should be entered as "14200"). If only one value present for 24 hour period, enter it as both the highest and lowest.	Required field.
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.
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.

APACHE III – PHYSIOLOGY (CONTINUATION)

DATA ITEM	DETAILS	LOGIC RULES
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.
13. Serum BUN*	Enter only highest value.	Required field.
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.
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.
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.
17. Serum Bilirubin*	Enter only highest value.	Required field.
18. Serum Bicarbonate*	Enter only lowest value.	Required field.

FORM: APACHE ARTERIAL BLOOD GASES

DAYS REQUIRED: **DAY 0**

INSTRUCTION: Record ALL ABGs in the 24 hours preceding RANDOMIZATION. **One** set of ABG values is required for the study. Select YES or NO to indicate if the patient was intubated (with or without positive pressure ventilation) when each ABG was obtained.

Select "New Copy" from the menu to the left of the form to create another copy of the row if there is more than one set of ABG values to enter. Repeat this process to record all available ABG values. Use the "Next Copy" and "Previous Copy" buttons to navigate between individual entries. Scroll through the lower section (see example below) at the bottom of the screen to view all entries at once.

NEW COPY
SAVE
EDIT
NEXT COPY
PREVIOUS COPY
NAVIGATE

FiO ₂	PaO ₂	PaCO ₂	pH	Intubated?	DATA RULES
					Required field.
					Record values, if available.
					Record values, if available.
					Record values, if available.
					Record values, if available.
					Record values, if available.
					Record values, if available.
					Record values, if available.
					Record values, if available.
					Record values, if available.

Click Load to display the corresponding entry in the CRF above

This table will appear at bottom of the screen when multiple entries are added.

Edit	fi02	pao2	paco2	ph	intubated
<u>Load</u>					
<u>Load</u>					
<u>Load</u>					

FORM: VITAL SIGNS-PRE RANDOMIZATION

DAYS REQUIRED: **DAY 0**

INSTRUCTION: VALUES SHOULD BE OBTAINED IN THE **4 HOUR INTERVAL THAT PRECEDES RANDOMIZATION**. IF THERE ARE NO VALUES AVAILABLE IN THIS 4 HOUR PERIOD, USE VALUES PRESENT WITHIN THE PRECEDING 24 HOURS. IF MORE THAN ONE VALUE IS AVAILABLE DURING THIS INTERVAL, RECORD THE VALUE **CLOSEST** TO THE TIME OF RANDOMIZATION.

DATA ITEM	DETAILS	LOGIC RULES
1. Heart Rate	Use last value prior to study initiation.	Required field.
2. Systolic BP	Use last value prior to study initiation.	Required field.
3. Diastolic BP	Use last value prior to study initiation.	Required field.
4. Mean Arterial Pressure	Enter the mean (MAP) of the values entered in 2 and 3 above in mmHg.	Required field.
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.
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. This value should be documented in the source documents (ie, pt chart or study file).	Required field.
7. PBW (Predicted Body Weight)	Enter Predicted Body Weight in kilograms. This value should be documented in the source documents (ie, pt chart or study file). Formula to calculate PBW: Males: $PBW = 50 + 2.3(\text{inches} - 60)$ Female: $PBW = 45.5 + 2.3(\text{inches} - 60)$	Required field.
8. Measured Weight	Enter most recent measured body weight. If weight not available during preceding 24 hours, enter most recent weight. Note technique for weighing patient (bed-scale, lift, etc.) on medical record.	Collect data, if available.
9. Anasarca	Select YES or NO to indicate presence of anasarca (generalized edema).	Required field.
10. Fluid intake last 24hrs	Enter the total amount of ALL fluids administered in the previous 24 hours in mL.	Required field.
11. FLUID output last 24hrs	Enter the total amount of ALL fluid output in the previous 24hrs in mL.	Required field.
12. Central venous pressure	Enter CVP value measured at end expiration in mmHg.	Required field if available.
13. Vasopressor or inotropic agents?	Select YES or NO to indicate if the pt has received any pressors or inotropics in the previous 24hrs.	Required field.

PRE-RANDOMIZATION VITAL SIGNS (CONTINUED)

DATA ITEM	DETAILS	LOGIC RULES
IF 13=YES ENTER THE INFUSION RATE AT THE TIME OF RANDOMIZATION FOR ALL THAT APPLY:		
13-1. Dopamine (≥6 mcg/kg/min)	Enter gtt rate at time of randomization in mcg/kg/min	Fields available if 13=YES
13-2. Norepinephrine (Levophed)	Enter gtt rate at time of randomization in mcg/min	
13-3. Epinephrine	Enter gtt rate at time of randomization in mcg/min	
13-4. Neo-Synephrine (Phenylephrine)	Enter gtt rate at time of randomization in mcg/min	
13-5. Dobutamine (Dobutrex)	Enter gtt rate at time of randomization in mcg/kg/min	
13-6. Dopexamine	Enter gtt rate at time of randomization in mcg/kg/min	
13-7. Milrinone	Enter gtt rate at time of randomization in mcg/kg/min	
13-8. Amrinone	Enter gtt rate at time of randomization in mcg/kg/min	
13-9. Vasopressin	Enter gtt rate at time of randomization in units/min	
13-10. Other	Select this option if the patient is on a pressor/inotrope that is not listed above.	
14. Diuretics?	Select YES or NO to indicate if the pt has received any diuretics in the 24hr period prior to time of randomization.	Required field.
If 14=YES THEN ENTER TOTAL DOSE ADMINISTERED IN THE 24HR PERIOD PRIOR TO TIME OF RANDOMIZATION		
14-1. Furosemide (Lasix)	Enter total dose in mg	Fields are available if 14=YES
14-2. Chlorthiazide (Diuril)	Enter total dose in mg	
14-3. Ethacrynic acid (Edecrin)	Enter total dose in mg	
14-4. Other	If diuretic is not listed above, select other at enter the total dose given. Use the comment field to enter the name.	

FORM: VENTILATOR PARAMETERS-BASELINE

DAYS REQUIRED: **DAY 0**

INSTRUCTION: CAPTURE THE MOST RECENT VALUES PRIOR TO **TIME OF RANDOMIZATION**.

DATA ITEMS	DETAILS	LOGIC RULES
1. Ventilator mode	Indicate what mode of ventilation the pt is receiving. Select all that apply: (SIMV, Pressure Support, Assist/Control, Pressure Control, PC IRV [inverse ratio ventilation], Other.	Required field.
2. Calculated delivered tidal volume	Enter the corrected inspired tidal volume: 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 (for these vents, the value set on the vent = the calculated delivered tidal volume).	Required field for SIMV and A/C modes.
3. Pressure Control Level	Enter the pressure control level (cm H ₂ O) on the ventilator if the patient is on Pressure Control Ventilation or PC IVR.	Required field for PC and PC IVR modes.
4. Pressure Support	Enter the level of Pressure Support (in cmH ₂ O) 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 for PS and SIMV +PS modes.
5. Set Rate	Enter the rate set on the ventilator if the patient is on 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.
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.
7. Total Minute Ventilation (VE)	Enter the total minute ventilation in liters per minute. This value is available from a digital report on the ventilator.	Required field.
8. PEEP	Enter the PEEP applied on the ventilator in cmH ₂ O. This is the external or applied PEEP, not the total PEEP, auto-PEEP, or intrinsic PEEP.	Required field.
9. Plateau Pressure (Pplat)	Enter the value for plateau pressure measurement in cm H ₂ O. The plateau pressure measurement should be made with a 0.5 second inspiratory pause.	
10. Peak Inspiratory Pressure	Enter the peak inspiratory airway pressure (cmH ₂ O). This should be obtained while the patient is relaxed, not coughing or moving in bed.	Required field for SIMV and A/C modes.
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.
12. Mean Airway Pressure	Enter the mean airway pressure (cmH ₂ O). This should be obtained while the patient is relaxed, not coughing or moving in bed.	Required field.

VENTILATOR PARAMETERS-BASELINE (CONTINUED)

DATA ITEM	DETAILS	LOGIC RULES
13. FiO2	Enter the fraction of inspired oxygen as decimal (e.g., ".50", not 50%)	Required field.
14, 15, 16: PaO ₂ , PaCO ₂ , and Arterial pH	Enter results of the last arterial blood gas prior to RANDOMIZATION	Required field.
17. SpO2	Enter pulse oximetry value prior to RANDOMIZATION. Observe the oximeter values for at least one minute and enter a representative value.	Required field.
INITIAL RECRUITMENT MANEUVER MEASUREMENTS	OBTAIN ITEMS 18-20 BELOW AFTER INITIAL VENT CHANGES (IF ANY) HAVE BEEN INITIATED. VALUES SHOULD BE OBTAINED ON A TIDAL VOLUME OF 6-8 ML/KG PBW BUT BEFORE OTHER PROTOCOL DIRECTED CHANGES	
18. Calculated delivered tidal volume	Enter the corrected inspired tidal volume: 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 (for these vents the value set on the vent = the calculated delivered tidal volume).	Required field.
19. Pplat	Enter the value for plateau pressure measurement in cm H ₂ O.	Required field.
20. PEEP	Enter the PEEP applied on the ventilator in cmH ₂ O. This is the external or applied PEEP, not the total PEEP, auto-PEEP, or intrinsic PEEP.	Required field.

FORM: CHEST X-RAY-BASELINE

DAYS REQUIRED: **DAY 0**

INSTRUCTION: Use the most recent chest radiograph prior to **TIME OF RANDOMIZATION**. This film may not necessarily be the "qualifying" x-ray that was used to determine ARDS onset.

DATA ITEM	DETAILS	LOGIC RULES
1. Number of quadrants with infiltrates.	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.
2. Barotrauma: Pneumothoraces	Select the appropriate item to indicate if there is a pneumothorax on the right side, on the left side, on both sides, bilateral, or none.	Required field.
Subcutaneous emphysema	Select (Yes) or (No) to indicate presence of subcutaneous emphysema apparent on the chest x-ray or by physical exam that is attributed to barotrauma.	Required field.
Pneumomediastinum	Select (Yes) or (No) to indicate if the chest x-ray shows air in the mediastinum attributed to barotrauma.	Required field.
Pneumatoceles > 2 cm diameter	Select the appropriate item to 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, the left side, on both sides, bilateral, or on neither side.	Required field.
3. Chest Tube	Select the appropriate item to indicate if there are one or more chest tubes on the right side, on the left side, on both sides, or on neither side.	Required field.

FORM: A-BASELINE LABS/ B-MIXED VENOUS AND CENTRAL VENOUS GASES-BASELINE

DAYS REQUIRED: **DAY 0**

INSTRUCTION A: (FOR LAB VALUES ONLY) RECORD VALUES CLOSEST TO THE TIME PRECEDING **RANDOMIZATION**. THESE LABS ARE REQUIRED FOR THE STUDY-IF A VALUE WAS NOT OBTAINED FOR CLINICAL PURPOSES, IT MUST BE DRAWN PRIOR TO THE FIRST FLUID MANAGEMENT INSTRUCTION.

DATA ITEM	DETAILS	LOGIC RULES
1. Hgb	Enter in g/dL	Required field.
2. WBC	Enter as "00000" (e.g., a WBC of 14.2 should be entered as "14200").	Required field.
3. Platelets	Enter as "000" (e.g., a platelet count of 258,000 should be entered as "258").	Required field.
4. Sodium	Enter serum sodium in mEq/L	Required field
5. Potassium	Enter serum potassium in mEq/L	Required field
6. Glucose	Enter serum glucose in mg/dL	Required field
7. Creatinine	Enter serum creatinine in mg/dL	Required field
8. BUN	Enter BUN in mg/dL	Required field.
9. Chloride	Enter serum chloride in mEq/L	Required field
10. HCO ₃	Enter serum bicarbonate in mEq/L	Required field.
11. Total protein	Enter serum total protein in g/dL	Required field.
12. Albumin	Enter serum albumin in g/dL	Required field.

INSTRUCTION B: (MIXED VENOUS AND CENTRAL VENOUS GASES) RECORD VALUES AFTER RANDOMIZATION (ONCE A CVC/PAC CATHETER IS IN PLACE) AND PRIOR TO THE FIRST FLUID MANAGEMENT INSTRUCTION. THESE VALUES ARE REQUIRED AT BASELINE; GASES MUST BE OBTAINED IF NOT AVAILABLE CLINICALLY.

MIXED VENOUS (mv) BLOOD GASES-FROM DISTAL PAC PORT (PAC only) :		
13. PmvO ₂	Enter the PmvO ₂ value obtained from a mixed venous blood sample (drawn from the distal PAC port).	Required field (PAC only: for CVC pts, mark field yellow ("missing data"))
14. PmvCO ₂	Enter the PmvCO ₂ value obtained from a mixed venous blood sample (drawn from the distal PAC port).	Required field (PAC only: yellow for CVC patients)
15. mv pH	Enter the pH value obtained from the mixed venous blood gas.	Required field (PAC only: yellow for CVC patients)
16. mvO ₂ Sat	Enter the SO ₂ value obtained from the mixed venous blood sample in %. (NOT the oximetry reading).	Required field (PAC only: yellow for CVC patients)
CENTRAL VENOUS (cv) BLOOD GASES FROM DISTAL PORT (CVC) OR PROXIMAL RA PORT (PAC). This Blood Sample Should be drawn SIMULTANEOUSLY (within one minute) with the mixed venous sample above for patients randomized to PA catheters (Pts randomized to CVC will require a central venous gas only):		
17. PcvO ₂	Enter the PcvO ₂ value obtained from a central venous blood sample.	Required field (CVC and PAC).
18. PcvCO ₂	Enter the PcvCO ₂ value obtained from a central venous blood sample.	Required field (CVC and PAC).
19. cvpH	Enter the pH value obtained from the central venous blood gas.	Required field (CVC and PAC).
20. cvO ₂ Sat	Enter the SO ₂ value obtained from the central venous blood sample in %.	Required field (CVC and PAC).

FORM: VITAL SIGNS-PRE FLUID MANAGEMENT

DAYS REQUIRED: DAY 0

INSTRUCTION: THIS FORM IS USED TO CAPTURE DATA IN THE PERIOD BETWEEN RANDOMIZATION TIME AND TIME OF THE FIRST FLUID MANAGEMENT ALGORITHM INSTRUCTION. IF MORE THAN ONE ITEM IS PRESENT, RECORD VALUES CLOSEST TO THE TIME PRECEDING THE FIRST INSTRUCTION.

DATA ITEM	DETAILS	LOGIC RULES
1. Date and time of FIRST fluid management instruction:	Enter values in the respective fields.	Required fields.
2. Mean Arterial Pressure (MAP):	Enter the mean of the blood pressure (MAP) closest to the time preceding the first fluid management instruction.	Required field.
3. Temperature	Use last value prior to the first instruction. Prefer rectal, tympanic, or core temperature. If axillary used, add 1 degree Centigrade or 2 degrees Fahrenheit.	Record if available.
4. Capillary refill time	Select the appropriate option to indicate if the capillary refill time is <=2 seconds or >2 seconds.	Required field.
5. Knee mottling?	Select YES or NO to indicate if skin mottling is present at the knee level.	Required field.
6. Cold extremities?	Select YES or NO to indicate if the patient's extremities are cold to touch.	Required field.
7. Fluid intake since time of randomization:	Enter the total amount of fluid in from randomization time to time of first instruction in mL.	Required field.
8. Fluid output since time of randomization:	Enter the total amount of ALL fluid output from randomization time to time of first instruction in mL.	Required field.
9. Central Venous Pressure (CVP):	Enter CVP value measured in mmHg at end expiration .	Required field.
10. Pulmonary Artery Systolic Pressure (PAS)	Enter the PAS value measured from the PA catheter in mmHg at end expiration .	Required for PAC pts. (CVC pts: mark yellow (missing data))
11. Pulmonary Artery Diastolic Pressure (PAD)	Enter the PAD value measured from the PA catheter in mmHg at end expiration .	Required for PAC pts. (mark yellow for CVC patients)
12. Pulmonary Artery Occlusion Pressure (PAOP or "wedge" pressure):	Enter mean PAOP measured from the PA catheter in mmHg at end expiration .	Required for PAC pts. (mark yellow for CVC patients)
13. Cardiac Index	Enter the cardiac index calculated from the cardiac output and the body surface area (CO/BSA=CI) in L/min/m ² . Enter the mean of the 3 output values.	Required for PAC pts. (mark yellow for CVC patients)
14. Mixed Venous O2 sat (Svo2)	Enter Svo2 (for PAC only). Can use oximetry reading from oximetric PAC.	Required for PAC pts. (mark yellow for CVC patients)
15. 4-hr urine output average	Enter the average urine output over the previous 4 hours prior to the first instruction in mL/kg/hr .	Required field.

VITAL SIGNS-PRE FLUID MANAGEMENT (CONTINUED)

DATA ITEM	DETAILS	LOGIC RULES
16. Vasopressor or inotropic agents?	Select YES or NO to indicate if the pt has received any pressors or inotropics in the previous 24hrs.	Required field.
IF 16=YES ENTER THE INFUSION RATE AT THE TIME OF FIRST FLUID INSTRUCTION FOR ALL THAT APPLY:		
16-1. Dopamine (≥6 mcg/kg/min)	Enter gtt rate at time of randomization in mcg/kg/min	Fields available if 16=YES
16-2. Norepinephrine (Levophed)	Enter gtt rate at time of randomization in mcg/min	
16-3. Epinephrine	Enter gtt rate at time of randomization in mcg/min	
16-4. Neo-Synephrine (Phenylephrine)	Enter gtt rate at time of randomization in mcg/min	
16-5. Dobutamine (Dobutrex)	Enter gtt rate at time of randomization in mcg/kg/min	
16-6. Dopexamine	Enter gtt rate at time of randomization in mcg/kg/min	
16-7. Milrinone	Enter gtt rate at time of randomization in mcg/kg/min	
16-8. Amrinone	Enter gtt rate at time of randomization in mcg/kg/min	
16-9. Vasopressin	Enter gtt rate at time of randomization in units/min	
16-10. Other	Select this option if the patient is on a pressor/inotrope that is not listed above.	
17. Diuretics?	Select YES or NO to indicate if the pt has received any diuretics in the period between randomization and time of first fluid instruction.	Required field.
If 17=YES THEN ENTER TOTAL DOSE ADMINISTERED SINCE RANDOMIZATION AND PRIOR TO FIRST FLUID INSTRUCTION		
17-1. Furosemide (Lasix)	Enter total dose in mg	Fields are available if 17=YES
17-2. Chlorthiazide (Diuril)	Enter total dose in mg	
17-3. Ethacrynic acid (Edecrin)	Enter total dose in mg	
17-4. Other	If diuretic is not listed above, select other. Use the comment field to enter the name.	

FORM: PAC/CVC ASSESSMENT-DAY 0 AND ON-STUDY

DAYS REQUIRED: **0-7**

INSTRUCTION: COMPLETE THIS FORM FOR ALL PAC OR CVC INSERTION/CHANGES TO DAY 7. Follow all catheters placed during the study (Days 0-7) for 3 days after removal to monitor for late complications. (i.e., a catheter placed on day 7 should be followed until day 10). USE ONE FORM FOR **EACH** CATHETER.

DATA ITEM	DETAILS	LOGIC RULES
1. Catheter number	Each catheter placed on study will be numbered (first study catheter =1).	Required field.
2. Catheter type	Select PAC, CVC, PICC or introducer.	Required field.
3. Insertion date and time.	Enter the date (mm/dd/yyyy) and time (military) that the catheter or introducer was inserted.	Required field.
4. Catheter placed through existing access?	Select YES or NO to indicate if this catheter was placed over a wire through an existing vascular access site.	Required field.
5. Catheter placed through new site?	Select YES or NO to indicate if this catheter was placed through a new vascular access site.	Required field.
6. Antibiotic coating?	Select YES or NO to indicate if this catheter is antibiotic coated.	Record if available.
7. Number of lumens	Enter the total number of lumens in this catheter.	Record if available.
8. manufacturer and model number	Enter the name of the manufacturer and the catheter model number in the spaced provided.	Required fields.
9. Catheter /introducer location	Select the appropriate option from the list provided that indicates where the catheter/introducer was placed.	Required field.
10. Date and time of catheter removal.	Enter the date (mm/dd/yyyy) and time (military) that this catheter was discontinued. (If this catheter was placed on day 7, follow until catheter is discontinued).	Required field.
11. Reason for removal.	Select the most appropriate option from the list provided.	Required field if date and time entered in 10.
12. Insertion complications (early)	Select all options that apply to document any complications that occur within the first 24hrs of insertion. If no complications occurred, select NO COMPLICATIONS.	Required field.
13. Late complications	Select from the list of complications all that occurred from 24hrs post insertion to 3 days after catheter removal . If no complications occurred, select NO COMPLICATIONS.	Required field.
14. Catheter tip cultured?	Select YES or NO to indicate if the catheter tip was sent for culture.	Required field; form complete if =NO.
15. If yes, culture results.	Enter the name of the identified organism(s) from the culture. Enter amount in CFU/mL if available.	Organism 1 field is enabled if 14 =YES.

FORM: DIAGNOSTIC STUDIES-BASELINE

DAYS REQUIRED: DAY -2 TO DAY 0

INSTRUCTION: ENTER THE DATE FOR ALL DIAGNOSTIC CARDIOVASCULAR STUDIES PERFORMED FROM 2 DAYS PRIOR TO RANDOMIZATION UP THROUGH DAY 0.

DATA ITEM	DETAILS	LOGIC RULES
1. Trans-thoracic cardiac ultrasound	Select YES or NO to indicate if this test has been performed in the specified time period. If YES, enter the date (mm/dd/yyyy).	Required fields; date fields are required for all YES answers.
2. Transesophageal cardiac ultrasound		
3. Radionuclide ventriculography		
4. Left heart cardiac catheterization		
5. Green dye cardiac output		
6. Bioimpedance cardiac output		
7. Other		

FORM: VITAL SIGNS/HEMODYNAMICS-ON STUDY

DAYS REQUIRED: **DAYS 1-7 (total fluid intake and output for day 7 is captured on day 8—complete only questions 11 and 12 on day 8 if patient on protocol through day 7)**

INSTRUCTION: CAPTURE VALUES CLOSEST TO 08:00 ON THIS CALENDAR DAY

DATA ITEM	DETAILS	LOGIC RULES
1. Heart Rate	Use the value closest to 08:00 in bpm.	Required field.
2a. Systolic BP	Use the values closest to 08:00 in mmHg.	Required field.
2b. Diastolic BP	Use the values closest to 08:00 in mmHg.	Required field.
3. Mean Arterial Pressure (MAP):	Enter the mean of the blood pressure (MAP) closest to the time preceding the first fluid management instruction.	Required field.
4. Temperature	Use last value prior to the first instruction. Prefer rectal, tympanic, or core temperature. If axillary used, add 1 degree Centigrade or 2 degrees Fahrenheit.	Required field.
5. Measured weight	Enter weight measured for this calendar day.	Required field if available.
6. Pt achieved hemodynamic stability this calendar date?	Select YES, NO, or N/A to indicate if protocol defined hemodynamic stability has occurred (absence of instruction for any of the following interventions by the fluid management strategy: fluid bolus, pressors, inotropes, and diuretics for a 24 hr period). See page15-16 of the protocol.	Required field.
If patient still on fluid management portion of the protocol, then questions 7-10 should be completed.		
7. Capillary refill time	Select the appropriate option to indicate if the capillary refill time is <=2 seconds or >2 seconds.	Required field.
8. Knee mottling?	Select YES or NO to indicate if skin mottling is present at the knee level.	Required field.
9. Cold extremities?	Select YES or NO to indicate if the patient's extremities are cold to touch.	Required field.
10. Anasarca?	Select YES or NO to indicate presence of anasarca (generalized edema).	Required field.
11. Fluid intake-last 24 hrs	Enter the TOTAL fluid intake for the last 24 hrs (a positive balance of CVVH fluid would count toward this total as a crystalloid)	Required field.
11-1. PRBCs	Enter the number of units of packed RBCs that the pt has received in the last 24hrs.	Required field.
11-2. FFP	Enter the number of units of fresh frozen plasma that the pt has received in the last 24hrs.	Required field.
11-3. 25% Albumin	Enter the amount of 25% albumin in mL that the pt has received in the last 24hrs.	Required field.
11-4. 5% Albumin	Enter the amount of 5% albumin in mL that the pt has received in the last 24hrs.	Required field.
11-5. Other colloid	Enter the amount in mL of any other colloid that the pt has received not listed above.	Required field.
11-6. Enteral	Enter the amount in mL of all enteral fluids that the pt has received in the last 24hrs in mL.	Required field.
12. Fluid output-last 24hrs	Enter the total amount of ALL fluid output for the last 24hrs in mL. (a negative balance of CVVH fluid would count toward this total).	Required field.

VITAL SIGNS/HEMODYNAMICS-ON STUDY (CONTINUED)

DATA ITEM	DETAILS	LOGIC RULES
13. Central Venous Pressure (CVP):	Enter CVP value measured in mmHg at end expiration .	Required field.
14. Pulmonary Artery Systolic Pressure (PAS)	Enter the PAS value measured from the PA catheter in mmHg at end expiration .	Required for PAC pts (mark yellow (missing data) for CVC patients)
15. Pulmonary Artery Diastolic Pressure (PAD)	Enter the PAD value measured from the PA catheter in mmHg at end expiration .	Required for PAC pts (yellow for CVC patients)
16. Pulmonary Artery Occlusion Pressure (PAOP or "wedge" pressure):	Enter mean PAOP measured from the PA catheter in mmHg at end expiration .	Required for PAC pts (yellow for CVC patients)
17. Cardiac Index	Enter the cardiac index calculated from the cardiac output and the body surface area (CO/BSA=CI) in L/min/m ² . Enter the mean of the 3 outputs.	Required for PAC pts (yellow for CVC patients)
18. Mixed Venous O2 sat (Svo ₂)	Enter Svo ₂ (for PAC only). Can use oximetry value from oximetric PAC, if available.	Required for PAC pts. (yellow for CVC patients)
19. Vasopressor or inotropic agents?	Select YES or NO to indicate if the pt has received any pressors or inotropics in the previous 24hrs.	Required field.
IF 19=YES ENTER THE INFUSION RATE AT 08:00 FOR ALL THAT APPLY:		
19-1. Dopamine	Enter gtt rate at time of randomization in mcg/kg/min	Fields available if 19=YES
19-2. Norepinephrine (Levophed)	Enter gtt rate at time of randomization in mcg/min	
19-3. Epinephrine	Enter gtt rate at time of randomization in mcg/min	
19-4. Neo-Synephrine (Phenylephrine)	Enter gtt rate at time of randomization in mcg/min	
19-5. Dobutamine (Dobutrex)	Enter gtt rate at time of randomization in mcg/kg/min	
19-6. Dopexamine	Enter gtt rate at time of randomization in mcg/kg/min	
19-7. Milrinone	Enter gtt rate at time of randomization in mcg/kg/min	
19-8. Amrinone	Enter gtt rate at time of randomization in mcg/kg/min	
19-9. Vasopressin	Enter gtt rate at time of randomization in units/min	
19-10. Other	Select this option if the patient is on a pressor/inotrope that is not listed above.	
20. Diuretics?	Select YES or NO to indicate if the pt has received any diuretics in the period between randomization and time of first fluid instruction.	Required field.
If 20=YES THEN ENTER TOTAL DOSE GIVEN ON THIS CALENDAR DATE:		
20-1. Furosemide (Lasix)	Enter total dose in mg	Fields are available if 20=YES
20-2. Chlorthiazide (Diuril)	Enter total dose in mg	

20-3. Ethacrynic acid (Edecrin)	Enter total dose in mg
20-4. Other	If diuretic is not listed above, select.
21. Recombinant human APC	Select YES or NO to indicate whether Xigris was given on this calendar date.

FORM: ON STUDY LABS

DAY(S) REQUIRED: SELECTED LABS REQUIRED ON **DAYS 1, 3, 5, AND 7**; RECORD IF AVAILABLE ON DAYS 2, 4, AND 6
 INSTRUCTION: RECORD VALUES OBTAINED WITH **MORNING LABS**, IF NOT AVAILABLE WITH MORNING LABS USE VALUES FROM THIS **CALENDAR DATE**. IF VALUE IS NOT CLINICALLY AVAILABLE IT MUST BE OBTAINED FOR THE REQUIRED DAYS LISTED.

DATA ITEM	DETAILS	LOGIC RULES
1. Hgb	Enter in g/dL	Required field.
2. Sodium	Enter serum sodium in mEq/L	Required field
3. Potassium	Enter serum potassium in mEq/L	Required field
4. Glucose	Enter serum glucose in mg/dL	Required field
5. Creatinine	Enter serum creatinine in mg/dL	Required field
6. BUN	Enter BUN in mg/dL	Required field.
7. Chloride	Enter serum chloride in mEq/L	Required field
8. HCO ₃	Enter serum bicarbonate in mEq/L	Required field.
9. Total protein	Enter serum total protein in g/dL	Required field.
10. Albumin	Enter serum albumin in g/dL	Required field.

FORM: VENTILATOR PARAMETERS-ON STUDY

DAYS REQUIRED: 1-4, 7, 14, 21, AND 28

INSTRUCTION: COMPLETE THIS FORM IF THE PATIENT IS ON **ASSISTED BREATHING** OR IS ATTEMPTING TO **WEAN**. USE VALUES FROM THE REFERENCE PERIOD 06:00-10:00; IF MORE THAN ONE VALUE AVAILABLE **USE THE VALUE CLOSEST TO 08:00**. If values not available during reference period, use value closest to 08:00 on that calendar date.

DATA ITEMS	DETAILS	LOGIC RULES
1. Calculated delivered tidal volume	Enter the corrected inspired tidal volume: 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 (for these vents the value set on the vent = the calculated delivered tidal volume).	Required field for SIMV and A/C modes.
2. Pressure Support	Enter the level of Pressure Support (in cmH ₂ O) 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 for PS and SIMV +PS modes.
3. 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).	Record if available.
4. 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.
5. Total Minute Ventilation (VE)	Enter the total minute ventilation in liters per minute. This value is available from a digital report on the ventilator.	Required field.
6. PEEP	Enter the PEEP applied on the ventilator in cmH ₂ O. This is the external or applied PEEP, not the total PEEP, auto-PEEP, or intrinsic PEEP.	Required field.
7. Plateau Pressure (Pplat)	Enter the value for plateau pressure measurement in cm H ₂ O. The plateau pressure measurement should be made with a 0.5 second inspiratory pause.	Record if available.
8. Peak Inspiratory Pressure	Enter the peak inspiratory airway pressure (cmH ₂ O). This should be obtained while the patient is relaxed, not coughing or moving in bed.	Record for SIMV and A/C modes.
9. 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: must complete either Set I:E or True I:E.
10. Mean Airway Pressure	Enter the mean airway pressure (cmH ₂ O). This should be obtained while the patient is relaxed, not coughing or moving in bed.	Record if available.
11. FiO ₂	Enter the fraction of inspired oxygen as decimal (e.g., ".50", not 50%)	Required field.
12-14: PaO ₂ , PaCO ₂ , and Arterial pH	Enter results of the arterial blood gas available closest to the reference period on this calendar date.	Required fields.

ON STUDY VENTILATOR PARAMETERS (CONTINUED)

DATA ITEM	DETAILS	LOGIC RULES
15. SpO ₂	Enter pulse oximetry value closest to 08:00 on this calendar date. Observe the oximeter values for at least one minute and enter a representative value.	Record if available.
MIXED VENOUS (mv) BLOOD GASES FROM DISTAL PAC PORT (PAC only):		
16. PmvO ₂	Enter the PmvO ₂ value obtained from a mixed venous blood sample (drawn from the distal PAC port).	Record if available.
17. PmvCO ₂	Enter the mvCO ₂ value obtained from a mixed venous blood sample (drawn from the distal PAC port).	Record if available.
18. mv pH	Enter the pH value obtained from the mixed venous blood gas.	Record if available.
19. mvO ₂ Sat	Enter the SO ₂ value obtained from the mixed venous blood sample in %. (If blood not available, enter oximetry reading from oximetric PAC, if available).	Record if available.
CENTRAL VENOUS (cv) BLOOD GASES FROM DISTAL PORT (CVC) OR PROXIMAL RA PORT (PAC):		
20. PcvO ₂	Enter the PcvO ₂ value obtained from a central venous blood sample.	Record if available.
21. PcvCO ₂	Enter the PcvCO ₂ value obtained from a central venous blood sample.	Record if available.
22. cv pH	Enter the pH value obtained from the central venous blood gas.	Record if available.
23. cvO ₂ Sat	Enter the SO ₂ value obtained from the central venous blood sample in %.	Record if available.

FORM: CHEST X-RAY-ON STUDY

DAYS REQUIRED: 1-7 when available

INSTRUCTION: USE THE FIRST CXR IN THE REFERENCE PERIOD 04:00-10:00. IF THERE IS NO X-RAY AVAILABLE IN THE REFERENCE PERIOD, USE THE FIRST CXR ON THIS CALENDAR DAY.

DATA ITEM	DETAILS	LOGIC RULES
1. Number of quadrants with infiltrates.	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.
2. Barotrauma: Pneumothoraces	Select the appropriate item to indicate if there is a pneumothorax on the right side, on the left side, on both sides, bilateral, or none.	Required field.
Subcutaneous emphysema	Select (Yes) or (No) to indicate presence of subcutaneous emphysema apparent on the chest x-ray or by physical exam that is attributed to barotrauma.	Required field.
Pneumomediastinum	Select (Yes) or (No) to indicate if the chest x-ray shows air in the mediastinum attributed to barotrauma.	Required field.
Pneumatoceles > 2 cm diameter	Select the appropriate item to 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, the left side, on both sides, bilateral, or on neither side.	Required field.
3. Chest Tube	Select the appropriate item to indicate if there are one or more chest tubes on the right side, on the left side, on both sides, or on neither side.	Required field.

FORM: DIAGNOSTIC STUDIES-ON STUDY

DAYS REQUIRED: 1-7, OR UNTIL UNASSISTED BREATHING OCCURS

INSTRUCTION: INDICATE ALL DIAGNOSTIC CARDIOVASCULAR STUDIES PERFORMED ON THIS CALENDAR DATE IF THE PATIENT IS STILL ON ASSISTED BREATHING.

DATA ITEM	DETAILS	LOGIC RULES
1. Trans-thoracic cardiac ultrasound	Select YES or NO to indicate if this test has been performed in the specified time period.	Required fields.
2. Transesophageal cardiac ultrasound		
3. Radionuclide ventriculography		
4. Left heart cardiac catheterization		
5. Green dye cardiac output		
6. Bioimpedance cardiac output		
7. Other		

FORM: RANDOM PROTOCOL CHECK

DAYS REQUIRED: 0-7 (*day "0" form only requires question number two*)

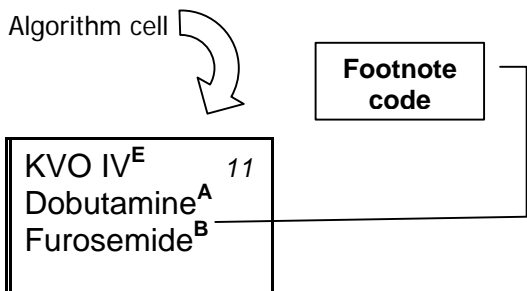
INSTRUCTION: PROTOCOL COMPLIANCE (ON-TARGET) CHECKS ARE CAPTURED TWICE PER DAY-1) **ON THE VITAL SIGNS/HEMODYNAMIC FORM AND 2) ON THE RANDOM PROTOCOL CHECK FORM.** COMPLETE THE FIELDS BELOW FOR THE RANDOM PROTOCOL CHECK TIME INDICATED (COMPUTER GENERATED) FOR EACH STUDY DAY.

DATA ITEM	DETAILS	LOGIC RULES
Random protocol check time: (computer generated)		
1. Fluid management protocol in effect?	Select YES or NO to indicate if the fluid management protocol is still in effect.	Required field.
1a. If no, give reason	Select the most appropriate reason from the list provided.	Required field if 1=NO. When a reason is entered, the form is complete.
2. Cell sequence:	Beginning with the first cell identified after midnight on this calendar date, enter the sequence of cells identified for EACH fluid management algorithm instruction. (<i>see bedside flowsheet</i>)	Required field.
3. Free water?	Select yes or no to indicate if free water (IV or PO) was administered on the date to treat hypernatremia.	Required field.
ENTER VALUES CLOSEST TO THE TIME PRECEDING THE RANDOM CATHETER CHECK TIME		
4. Time of data collection	Enter the time (military) that the data was collected. The time closest and prior to the random cath check time should be selected. Values should be taken from a time where a FULL set of hemodynamic data is available.	Required field.
5. MAP (mean arterial pressure)	Enter the mean of the blood pressure (MAP) closest to the time preceding the random cath check.	Required field.
5a. On vasopressors?	Enter yes or no to indicate if the subject was on vasopressors at the time of the computer-generated time.	Required field.
6. Adequate circulation?	Select YES or NO to indicate if criteria for adequate circulation have been met: Capillary refill < 2 sec., absence of knee mottling, and extremities warm to touch.	Required field.
7. CVP (central venous pressure)	Enter CVP value measured in mmHg at end expiration .	Required field.
8. PAOP (pulmonary artery occlusion pressure)	Enter mean PAOP measured from the PA catheter in mmHg at end expiration .	Required field: PAC patients only. CVC pts: mark with yellow (missing data).
9. Assumed PAOP from PAD estimate.	If catheter unable to wedge or if PAOP invalid value, enter the assumed PAOP based on PAD (pulmonary artery diastolic pressure). See protocol appendix I, section G pg 29 for instruction on estimating PAOP from PAD.	PAC patients only.
10. PAD (pulmonary artery diastolic pressure)	Enter the PAD value measured from the PA catheter in mmHg at end expiration .	Required field: PAC patients only. CVC pts: mark with yellow.
11. Cardiac Index (CI)	Enter the cardiac index calculated from the cardiac output and the body surface area (CO/BSA=CI) in L/min/m ² . Enter the mean of 3.	Required field: PAC patients only. CVC pts: mark with yellow.

RANDOM PROTOCOL CHECK (CONTINUED)

DATA ITEM	DETAILS	LOGIC RULES
12. Mixed venous O2 sat	Enter SvO2 if available. Can use oximetry reading from oximetric PAC, if available.	Required field.
13. PEEP	Enter the PEEP applied on the ventilator in cmH ₂ O. This is the external or applied PEEP, not the total PEEP, auto-PEEP, or intrinsic PEEP.	Required field.
14. 4 hr urine output average	Enter the average of the urine output, In mg/kg/hr , from the 4 hour period (or since last assessment) prior to the data collection time entered in #4 above. <i>(If patient is on CVVH or HD, record the <u>actual</u> UOP and add the comment "renal replacement" to the field).</i>	Required field.
15. Fluid management cell number.	Enter the fluid management algorithm CELL NUMBER that was selected by the ICU team from the above data. Algorithm cell number range: 1-20. <i>See bedside data collection sheet.</i>	Required field.
<p>Below is the list of possible treatments from the fluid management algorithm. Note which ones have been given in response to the data entered above. For those treatments that = NO enter 1) the applicable footnote code* (if not given because of footnote) OR 2) the reason the treatment was declined.</p>		
16.1-16.4 Enter treatments given in response to data in questions 5-11, 14:		
Treatments given?: Vasopressor Fluid Bolus Dobutamine Lasix	Select YES or NO to indicate whether each treatment has been given.	Required fields.
If not given, why not?	Select appropriate reason that treatment was not given.	Required field for all NO answers in first section.
If Treatments given = NO, complete this section:	Use pulldown menu and select most appropriate response.	Required field for all NO answers in first section.

* The **footnote code** is denoted by a letter superscript next to the treatment in the indicated cell of the fluid management algorithm. Definitions of footnote codes are listed on pages 28-30 of the protocol.




FORM: PROTOCOL VALIDATION FORM

DAYS REQUIRED: **0-7**

INSTRUCTION: THIS FORM IS REQUIRED DURING THE **VALIDATION PHASE** OF THE PAC STUDY. ALL DATA REGARDING THE FLUID MANAGEMENT PROTOCOL WILL BE COLLECTED AND REVIEWED IN THIS PHASE. START THIS FORM WITH THE FIRST FLUID MANAGEMENT INSTRUCTION ON DAY 0. DATA WILL BE CAPTURED (BY ICU NURSE) ON THE BEDSIDE DATA COLLECTION SHEET AT A MINIMUM OF EVERY 4 HOURS.

DATA ITEM	DETAILS	LOGIC RULES
1. Date and time of date collection.	Enter the date (mm/dd/yyyy) and time (military) that the set of data, used to generate this fluid management instruction, occurred. (1 st column on the bedside data sheet.)	Select NEW COPY for each set of data
2. Cell number used by ICU team	Enter the cell number that the ICU team selected based on the data entered for the date and time in #1. (3 rd column on the bedside data sheet.)	Required field.
3-7: Enter treatments given in response to data from the bedside data collection sheet:		
Treatments given?: Vasopressor Fluid Bolus Dobutamine KVO IV Lasix	Select YES or NO to indicate whether each treatment has been given. Select NOT IN CELL if the treatment is not listed in the cell indicated.	Required fields
Treatment not given because of footnote?	Select YES or NO to indicate if the treatment was declined due to a footnote. The footnote code is denoted by a letter superscript next to the treatment in the indicated cell of the fluid management algorithm (from cell # entered in item 2 above). Definitions of footnote codes are listed on pages 28-30 of the protocol.	Required field for all NO answers in first section.
If Treatments given = NO, complete this section:	<ol style="list-style-type: none"> From pull-down menu, select applicable footnote codes which best describe why the treatment was not given. OR Select a reason from the picklist for all treatments declined which were not due to a footnote. If the reason is not available in the list select OTHER and enter the reason in the "Other" text field. 	All items with a NO answer in the first section require either a footnote code or a decline reason in this field.

 Select "NEW COPY" from the menu to the left of the form to create a new form for EACH instruction. Repeat this process to record all fluid management instructions. Use the "Next Copy" and "Previous Copy" buttons to navigate between individual entries. Scroll through the lower section at the bottom of the screen to view all entries.

FORM: WEANING

DAYS REQUIRED: 1-28 OR UNTIL UNASSISTED BREATHING ACHIEVED

INSTRUCTION: OBTAIN THESE VALUES EVERY DAY TO DAY 28 OR UNTIL UNASSISTED BREATHING IS ACHIEVED, WHICHEVER COMES FIRST.

DATA ITEM	DETAILS	LOGIC RULES
1. Did pt meet weaning criteria?	Enter YES, NO, or NOT TRIED/EVALUATED to indicate if the patient met all of the following criteria: (a) ≥ 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. <i>See Appendix II page 35 of the protocol for further detail on weaning criteria.</i>	Required field.
2. Did pt pass 5-min CPAP trial?	Select YES if a 5-minute CPAP trial was conducted and the patient's respiratory rate remained ≤ 35 breaths/min. Select NO if RR > 35 during the CPAP trial. Select Not tried/Evaluated if the CPAP trial was not conducted (<i>see appendix II pg 36</i>).	Required if 1 =YES.
3. Did pt tolerate a trial of spontaneous breathing?	Select YES, NO, or NOT TRIED/EVALUATED to indicate if the patient tolerated a trial of spontaneous breathing > 2 hrs. Spontaneous breathing trial = CPAP 5, T-piece, or trach mask with $FiO_2 \leq .50$. (<i>The pt must meet all criteria specified in Appendix II, pg 37 of the protocol.</i>)	Required field.
4. 48 hours of Unassisted Breathing completed?	Select YES or NO to indicate if patient COMPLETED 48 hours of "Unassisted Breathing" on this calendar date. See Appendix II pg 38 of the protocol for definition of "Unassisted Breathing" .	Required field.
STERIODS AND EXPERIMENTAL THERAPIES:		
5. IV or PO steroids this calendar date?	Enter YES or NO to indicate if corticosteroids were given on this calendar date. If yes, enter the amount in mg of methylprednisolone equivalents. (<i>See steroid equivalency SOP in study binder</i>).	Required field; amount required if 5=YES.
6. Experimental therapies:	Select YES or NO to indicate if the pt received any experimental therapies on this calendar date. If yes, select all that apply from the list. ECMO= <i>Extracorporeal Membrane Oxygenation</i> IVOX= <i>Intravascular Oxygenation Device</i> HFV= <i>High Frequency Ventilation</i> HFO= <i>High Frequency Oscillation</i> PGI= <i>Prostaglandin-I</i> PGE= <i>Prostaglandin-E</i>	Required field; list is enabled if 6 =YES.

FORM: BLOOD CULTURE

DAYS REQUIRED: 0, 1-10 (if positive blood culture for that day)

INSTRUCTION: RECORD ALL POSITIVE BLOOD CULTURES OCCURRING FROM STUDY ONSET (DAY 0) UNTIL 3 DAYS AFTER REMOVAL OF THE LAST STUDY CATHETER (PAC OR CVC). CATHETERS CAN BE IN PLACE UP TO DAY 7; THEREFORE, COLLECTION OF BLOOD CULTURES COULD BE INDICATED UP TO DAY 10.

DATA ITEM	DETAILS	LOGIC RULES
Organism	Select the corresponding organism for each positive culture from the list provided. If the organism is not listed, select OTHER.	Required field for items with a date entered.
Date	Enter the date (mm/dd/yyyy) that each blood culture was COLLECTED not the date that the results were reported	Record if available
Time	Enter the time (military) that each blood culture was COLLECTED.	Required field for each item with a date entered.

Select "New Copy" from the menu to the left of the form to create another copy of the form if there is more than one blood culture to enter. Repeat this process to record all on-study positive blood cultures. Use the "Next Copy" and "Previous Copy" buttons to navigate between individual entries. Scroll through the lower section (see example below) at the bottom of the screen to view all entries at once.

Click Load to display the corresponding entry in the CRF above

This table will appear at bottom of the screen when multiple entries are added.

Edit	date	time	organism
<u>Load</u>			
<u>Load</u>			
<u>Load</u>			

FORM: GLASGOW COMA SCORE (GCS)

DAYS REQUIRED: **0, 7, AND HOSPITAL DISCHARGE (or day 28, whichever comes first)**


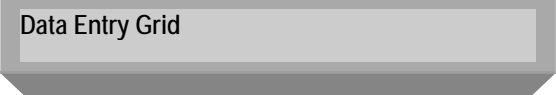
INSTRUCTION: USE THE OPTIONS LISTED ON THE CRF TO CALCULATE THE WORST GCS FOR THIS CALENDAR DATE. ALL THREE COMPONENTS SHOULD ORIGINATE FROM THE SAME TIME POINT.


DATA ITEM	DETAILS	LOGIC RULES
1. Pt on sedative or neuromuscular blocker?	Select YES or NO to indicate if the pt was sedated or receiving a paralytic at time of GCS assessment.	Required field.
2. Eye Opening Score	Select the option that indicates the best response. If patient's eyes are swollen shut, estimate best response.	Required field.
3. Motor Response Score	Select the option that indicates the best response.	Required field.
4. Verbal Response Score	Select the option that indicates the best response. If patient was intubated on this date select from the "on vent" pick-list and use clinical judgment to estimate best response. If unsure, enter "3-questionably oriented".	Required field.
GCS-total score:	Computer calculated total Glasgow Coma Score.	Calculated value.

FORM: **BRUSSELS TABLE**

DAYS REQUIRED: **DAILY UNTIL DAY 28.**


INSTRUCTION: COMPLETE THIS FORM USING *CLINICALLY AVAILABLE* DATA ON ALL DAYS UNTIL DEATH OR STUDY HOSPITAL DISCHARGE, WHICHEVER COMES FIRST. **NOTE:** SEE PROTOCOL TO IDENTIFY LABS THAT ARE **REQUIRED** ON CERTAIN DAYS.

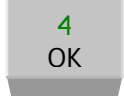
Date	Systolic BP	P/F	Platelets	Creatinine	Bilirubin	Vasopressor
<input type="text"/> 	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> No Answer <input type="checkbox"/> Yes (1) <input type="checkbox"/> No (2)
						


 Data can be entered in the form above. Select NEW COPY from the menu to the right of the form to enter data for each day OR use the pop-up table on the Brussels form to enter data for multiple days. **Click on the DATA ENTRY GRID button to access the table.** Data can be entered either across or down in the table.

* 1) You must be in the **ABOVE FORM** to utilize the **MISSING DATA** option; it is not accessible from the data entry grid. 2) The Brussels form **MUST** be "activated" (selecting and opening day 0) prior to initiating a study termination form.

Data Entry Grid:

 Quick Entry					
	Date	SBP	P/F	Platelets	Creatinine
Day 0	01/11/2000				
Day 1	01/12/2000				
Day2	01/13/2000				





I. In the row labeled "Day 0", enter data pertaining to the date of enrollment from the **time immediately following initial study procedures until 2359.59 (11:59.59 pm)**. If no values are available during this interval, enter most recent values from before this interval.

II. In the rows for Days 1-7, 14, 21, and 28, enter data from 0000 (Midnight) until 23:59.59 for each calendar date.

III. Record the worst values for each of the five variables shown at the headings of the columns. **Worst values are defined as:**

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.

IV. Vasopressors yes/no: Enter "1" (Yes) to indicate that one or more vasopressors were used on the calendar date. Enter "2" (No) 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.

FORM: ADVERSE EVENT REPORTING

DAYS REQUIRED: DAY 0-21, OR UNTIL ICU DISCHARGE, WHICHEVER OCCURS FIRST

INSTRUCTION: This form should be used to capture All **CLINICALLY IMPORTANT and UNEXPECTED** adverse events that occur from time of initiation of the first study procedure until study day 21 or until ICU discharge, whichever occurs first. See page 22 of the protocol for description of reporting procedures.

Deaths will be captured on the study termination form and will NOT require a “death report form”. Deaths resulting from an adverse event will fall under the reporting requirements of an **IMMEDIATELY REPORTABLE AE** outlined below.

The Adverse Event Form should not be used as the primary method to capture organ failures related to ARDS; these are systematically captured by the protocol.

IMMEDIATELY REPORTABLE AE= SERIOUS + UNEXPECTED + STUDY RELATED:
 All **SERIOUS AND UNEXPECTED AND STUDY-RELATED** adverse events should be reported to the Clinical Coordinating Center *within 24 hours by phone*. The investigator must submit a detailed, written report to the Clinical Coordinating Center within **5 working days**. The Institutional Review Board should be notified based on institutional policy, but no later than 5 working days after the event is discovered.

☒ **NOTE:** To report a serious AE that occurs over the weekend page the **on-call investigator**.

☒ To report multiple events on the same patient: 1) go to the study day that the event occurred and open the AE form for that day, OR 2) click on **NEW COPY** in the menu to the left of the form to create another copy of the AE form. Use **NEXT COPY** and **PREVIOUS COPY** from the menu to move between copies. When there are 2 or more copies a summary view is present at the bottom of the screen: Use the scroll bar on the right to see all copies. You can go directly to each form by clicking on **LOAD** next to each record in the summary view.

☒ A COMPUTER FILE OF THE **COSTART** PICKLIST IS REQUIRED TO COMPLETE #3 ON THE FORM. *SEE SOP ON ACCESSING THE COSTART FILE.* SELECT THE **BEST** TERM FROM THE SEARCH WINDOW, THEN HIGHLIGHT IT AND CUT AND PASTE INTO QUESTION 3.

* **NOTE:** To view any **queries** or **comments** entered on an AE form, you must access the form from the **STUDY DAY** that it was **INITIALLY** opened. Click on the **“MULTIPLE COPIES”** option to the right of the adverse event form in the **HOME** view to see where a query or comment is located.

ITEM	DEFINITION	DATA RULES
1. Date of event	☒ Enter the date (mm/dd/yyyy) or select the date from the pop-up calendar that the event first occurred.	Required field.
2. Time of event	Enter the time (military) the event began.	Required field.
3. Name of event	☒ Select the term from the COSTART pick-list (located in the COSTART file on your computer) that BEST categorizes the event.	Required field.
4. Description of the event	Give a brief narrative description of the event. Include: ➤ Course of events that lead to the AE, ➤ Relationship of the time of the event to the time of a study procedure, if applicable. ➤ Include same elements for description of a death for a fatal AE.	Required field.

AE FORM (CONTINUED)

DATA ITEM	DETAILS	LOGIC RULES
5. Severity of event	Select one: MILD -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. SERIOUS -Any event that if fatal or immediately life threatening, is permanently disabling, or severely incapacitating, or requires or prolongs inpatient hospitalization. SEE APENDIX III, pg 39 IN THE PROTOCOL FOR DEFINITIONS OF AEs.	Required field. CCC MUST BE NOTIFIED WITHIN 24 HOURS FOR SERIOUS, UNEXPECTED AND STUDY RELATED EVENTS!!!!
6. Therapeutic intervention?	Select YES or NO to indicate if therapeutic intervention was required to prevent permanent impairment or damage.	Required field.
7. Immediate risk of death?	Select YES or NO to indicate if the event was immediately life threatening to the pt.	Required field.
8. Unexpected or more severe than expected in CVC/PAC managed ARDS or ALI?	Select YES, NO, or UNKNOWN to indicate if the event is unexpected in CVC/PAC managed ARDS/ALI or more severe or frequent than expected in CVC/PAC managed ARDS/ALI.	Required field.
9. Causal relationship to PAC/CVC?	Select the answer, which best describes the event's relationship to the <u>PAC/CVC</u> and to the <u>Fluid Management Protocol</u> . 1= Definitely Associated- The event follows: a) A reasonable, temporal sequence from a study procedure; b) Cannot be explained by the known characteristics of the patient's clinical state or other therapies; c) Evaluation of the patient's clinical state indicates to the investigator that the experience is definitely related to study procedures.	Required fields.
10. Casal relationship to Fluid Management Protocol?	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 patient's 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.	
11. Withdrawn from study?	Select Yes or NO to indicate if the patient was withdrawn from the protocol BECAUSE of this event. If YES, select all options that apply from the list provided.	Required field.
12. Status of the EVENT at time of initial AE report.	Select Recovered, date, AE present, no tx, AE present, being treated, Residual effect/no tx, Residual effect/being treated, or Deceased as a result of this event. <i>Select deceased ONLY if the patient died as a result of the event.</i>	Required field.
If recovered, date	If the answer selected is Recovered, select the date (either from the pop-up calendar or enter in mm/dd/yyyy) of recovery from the event.	Required field if "recovered" selected. Form is complete if #11=recovered/dated
13. FINAL outcome of AE	The patient should be followed until the reported event is RESOLVED or stabilized. Enter the date (mm/dd/yyyy) of resolution.	Required fields if #12 = 2,3,4, or 5.

FORM: SPECIMEN COLLECTION

DAYS REQUIRED: 0, 1, 3, AND 7

INSTRUCTION: DRAW BLOOD SPECIEMS FOR CYTOKINES ON DAYS 0,1,3, AND 7. SAMPLES CAN BE COLLECTED ± 1 DAY FROM REQUIRED DAY.

Collect plasma for blood cytokines as follows:

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 with plasma (1 ML OF PLASMA IN EACH OF 12 TUBES).
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.

GENETIC SAMPLES: Please refer to Appendix IV (Genetic Testing Procedures)


DATA ITEM	DETAILS	LOGIC RULES
DAY 0 BLOOD DRAW	Select YES or NO to indicate if the blood sample was collected on the days required. Enter the date drawn for each sample collected. Enter a comment to note any samples that were drawn ± 1 day from specified study day.	Y/N: required field for each day indicated. Date fields required for all YES answers.
DAY 1 BLOOD DRAW		
DAY 3 BLOOD DRAW		
DAY 7 BLOOD DRAW		
GENETIC SAMPLES: 1) WHOLE BLOOD 2) BUCCAL SMEAR	Select YES or NO to indicated if the blood sample and buccal smear was collected. Enter the date the samples were collected.	Y/N required fields. Date fields required for YES answers.

FORM: STUDY TERMINATION




DAYS REQUIRED: **DAY 28 AND UP THROUGH DAY 90**

INSTRUCTION: **BEGIN COMPLETION OF THIS FORM BY DAY 28.**

- I. Enter data in question 1 by Day 28. If status at Day 28 is "other" and changes prior to Day 90, **update this field to reflect the change.**
- II. PATIENTS WHO ARE NOT YET HOME WITH UNASSISTED BREATHING (UAB) SHOULD BE FOLLOWED THROUGH DAY 90.
- III. **Up to Day 90 Capture:** 1) ICU discharge date (and ALL ICU re-admissions in study hospital if applicable); 2) Study hospital discharge date AND vital status at discharge; and 3) On/Off assisted breathing dates.

ITEM	DEFINITION	DATA RULES
1. Patient Status (through Day 90):	<p>Select "home with UAB" if the patient is home with unassisted breathing at any time up through day 90. "Home" is defined as the place the patient lived prior to study hospital admission (i.e., pt living in a nursing home→admitted to study hospital and enrolled into PAC study→dc'd back to nursing home on UAB. The nursing home would qualify as "home on UAB". Pts previously living at home who are discharged to a rehab facility on UAB from study hospital would NOT qualify as being "home on UAB".)</p> <p>Select "Dead..." if the patient died prior to discharge home with unassisted breathing or died prior to achieving unassisted breathing at home for 48 hours.</p> <p>Select "Other" if neither condition above applies. E.g., if the patient went home on assisted breathing and has not achieved unassisted breathing for 48 hours, continues on assisted breathing, or has been transferred to another facility, other than home, on unassisted breathing.</p>	Required field.
1a,b,c. Dates	<p> Select the appropriate date (from the pop-up calendar) 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 date of last KNOWN patient status, i.e., date that the patient was last know to be alive and does not meet the other 2 criteria (if condition 3 above).</p>	Required field. There should be only ONE date entered to correspond with the selected status option.
2. Was pt permanently withdrawn fluid management arm of the trial? 2a. If yes, give date	<p>Select either YES or NO to indicate if the patient was <i>withdrawn</i> from participation in 1) PAC/CVC or 2) fluid management protocol. Do NOT answer "yes" for patients who have met criteria for COMPLETION of the protocol.</p>	Required field.
3. Patient discharged alive from study hospital?	<p>Select the option (yes/no) that applies to indicate if the patient was discharged alive from the study hospital up through Day 90.</p>	Required field.
3a. Date	<p>If 3= Yes, give the date of discharge.</p>	Required field if 3= Yes.
3b. Destination at discharge:	<p>If patient is alive, select location after discharge from list.</p>	Required.

STUDY TERMINATION FORM (CONTINUED)

DATA ITEM	DETAILS	LOGIC RULES
<p>FOR QUESTION 4a-e DOCUMENT ALL INCIDENCES OF ICU ADMISSIONS AND DISCHARGES <u>DURING THE STUDY HOSPITALIZATION</u> UP THROUGH DAY 90</p>		<p>Questions are required until a "No" or "Unknown" response is selected, then skip to 5a.</p>
<p>4a. Was the patient discharged from an ICU? If yes, enter date.</p>	<p>Select the option that best applies.  Select the date of discharge from the pop-up calendar by clicking on the "date" button.</p>	<p>Required field. Date required if "Yes" selected.</p>
<p>4b. Pt readmitted to an ICU? If yes, enter date.</p>	<p>Was the pt readmitted to an ICU during study hospitalization? This includes any ICU within the study hospital. Select the option that best applies.  Select the date of readmission from the pop-up calendar.</p>	<p>Required field if 4a=yes. Date required if "Yes" selected.</p>
<p>Discharged after ICU readmission? If yes, enter date.</p>	<p>Was the pt discharged (alive or dead) after readmission to the ICU? Select the option that best applies.  Select the date of discharge from the pop-up calendar.</p>	<p>Required field if #4b =Yes. Date required if "Yes" selected.</p>
<p>4c. If 4b= Yes, was pt readmitted a 2nd time? If yes, enter date.</p>	<p>Was the pt readmitted to an ICU at any time after the DC date entered in 4b? If yes, enter the date of the 2nd readmission.</p>	<p>Required field if a DC date is present in 4b.</p>
<p>4d-e.</p>	<p>Use these questions to capture all other ICU readmissions and discharges, occurring in study hospital, up through Day 90 when applicable.</p>	
<p>VENTILATOR HISTORY: FOR QUESTIONS 5a-g CAPTURE ALL INCIDENCES OF UNASSISTED BREATHING UNTIL DC HOME, DEATH, OR UNTIL PT HAS BEEN FOLLOWED TO DAY 90</p> <p>A VENTILATOR DAY IS ANY DAY IN WHICH THE PT RECEIVED ASSISTED BREATHING; EXCEPTION: ASSISTED BREATHING FOR <24 HRS FOR A PROCEDURE OR SURGERY.</p>		<p>Questions are required until a "No" or "Unknown" response is selected, then skip to 6.</p>
<p>5a. Did pt achieve unassisted breathing?</p>	<p>Select the option that applies. See appendix II, pg 38 of the protocol for definition of unassisted breathing.</p>	<p>Required field.</p>
<p>Date of the FIRST episode of UAB:</p>	<p>Select the first date that the pt was on UAB from midnight to midnight (i.e., If the pt was extubated on Day 2 and remained off the vent through Day 3, Day 3 would be the date of first UAB).</p>	<p>Required field if UAB =Yes.</p>
<p>5b. Did pt return to assisted breathing? If yes, enter date.</p>	<p>Select the option that best applies. If Yes, enter the date that the pt returned to assisted breathing.</p>	<p>Required field if 6a =Yes.</p>

STUDY TERMINATION (CONTINUED)

DATA ITEM	DETAILS	LOGIC RULES
5c. If pt returned to assisted breathing, was a 2 nd episode of UAB achieved?	Select the option that best applies. If yes, enter the SECOND date that the pt was on UAB (from midnight to midnight).	Required field if 6b =Yes.
5d. Pt returned to assisted breathing after 2 nd episode of UAB?	Select the option that best applies. If yes, enter the date that the pt returned to assisted breathing after the 2 nd period of UAB.	Required field if 6c = Yes.
5e-g.	Use these questions to capture ALL other incidences of UAB occurring at any location until dc home, death, or pt is followed to Day 90.	
6. Did pt require dialysis?	<p>Select YES or NO to indicate if the pt received dialysis during study hospitalization. Dialysis includes-hemodialysis, peritoneal dialysis, CVVH, and CAVH.</p> <p>If yes, enter the start date that the first dialysis was initiated and the last date that dialysis was required during study hospitalization.</p>	Y/N answer required. Date fields required for YES answer.
7. End of Life Decision Making:	<p>This field is intended to capture information on end of life decision making for <u>all pts who died</u>. "Life Support" includes (but is not limited to): mechanical ventilation, vasopressors, IV fluids, antibiotics, dialysis, and blood products. *Select the option that best applies:</p> <ol style="list-style-type: none"> 1) No DNR decision made (includes pts receiving aggressive management, including failed CPR) 2) DNR Decision made: withhold only CPR (includes pts receiving aggressive management up to <i>but not including</i> CPR) 3) DNR Decision made: withhold life support <i>in addition to</i> CPR. (Includes pts with an identified antemortem decision to withhold some form of life support, i.e., in the event of renal failure will not dialyze or if respiratory failure occurs will not re-intubate). 4) DNR Decision made: withdraw life support (includes removal of mechanical ventilation, dialysis, or discontinuation of vasopressors or antibiotics). 5) Diagnosis of Brain Death (per study site institutional standards for brain death criteria). 6) Unknown/can't tell 	Required.

* Criteria for DNR grading adapted from: Prendergast T, Claessens M, and Luce J. *A National Survey of End-of-life Care for Critically Ill Patients*. Am. J. Respir. Crit. Care Med., Volume 158, Number 4, October 1998, 1163-1167