COORDINATOR INSTRUCTIONS

Note: The purpose of these instructions is to briefly cover some of the important points regarding the Case Report Forms. Please refer to the Manual of Operations for more comprehensive coverage.

This binder contains the forms and worksheets for one patient who has been randomized into the GLND study.

Please refer to the Table of Contents, which is provided on the next page, when attempting to locate forms, logs and/or worksheets.

1. Screening Forms

   You should place the following forms in the Screening Forms section:

   -Screening Form
   -Eligibility Criteria Confirmation Form
   -APACHE II Scoring Form

2. PI Sign-Off Form - Patient Enrollment

   After the patient is randomized and the Screening, Eligibility Criteria Confirmation and APACHE II Scoring Forms are completed, have the site Principal Investigator fill out the PI Sign-Off Form, fax it to the DCC, and return it to this binder.

3. Baseline Forms

   At Baseline, complete the following forms:

   -Demographics/History Form
   -Baseline Plasma & Serum Storage Form
   -Concomitant Medications Form

   Note: Complete the Baseline Plasma & Serum Storage Form BEFORE the PN bag is hung.

4. Definition of a Day

   Be familiar with the definition of a day in this study. Day 1 officially begins at your institution's PN hang time on the date the study drug is started. A day is defined as the 24-hour period beginning at your institution's PN hang time and ending the following day. Please use this definition when filling out all the follow-up forms and worksheets associated with them, as appropriate.

5. Blood Draws

   Day 3, 7, 14, 21 and 28 Blood Draws must take place REGARDLESS of when the patient is discharged. If the patient is discharged anytime before Day 28, make sure you schedule the appropriate Blood Draws.

6. Nosocomial Infections

   All suspected nosocomial infections should be recorded, beginning with existing suspected infections at patient randomization. Fill out the Suspected Nosocomial Infections Log and a separate CRF for each determined nosocomial infection, or suspected but undetermined nosocomial infection. Refer to Section 9.1.b and Appendix 7 of the Study Manual of Operations for infection diagnosis procedures, definitions and codes. Appendix 7 is also available in the Suspected Nosocomial Infections Log section for your convenience.

TABLE OF CONTENTS

SCREENING FORMS

TAB PAGE

Move the following forms from the Screening Binder to this section once the patient is enrolled in the study:

1. Initial Screening Form
2. Eligibility Criteria Confirmation Form
3. APACHE II Scoring Form

PI SIGN-OFF FORM: PATIENT ENROLLMENT

TAB PAGE

DataFax #012 Plate #007 Visit #000

GLND **PI SIGN-OFF FORM: PATIENT ENROLLMENT** **Page 1 of 1**

The site Principal Investigator should review the Screening, Eligibility Criteria Confirmation and APACHE II Scoring Forms and complete and sign this form when the patient is randomized.

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*) Form Completed By (Initials): ☐☐☐ (*F M L*)

Date Form Completed: ☐☐ (*month*) ☐☐ (*day*) ☐☐ (*year*)

I have reviewed the Screening, Eligibility Criteria Confirmation, APACHE II Scoring Forms, and related documents pertaining to the patient screening and enrollment, and have verified that they accurately reflect source documentation for this patient.

Investigator Name *(please print)*

☐ *VALIDATION:* Mark box if signature provided.

Investigator Signature

Fax this form to the Data Coordinating Center toll free at 866-477-1298.

PATIENT CONTACT INFORMATION FORM

TAB PAGE

GLND **PATIENT CONTACT INFORMATION** **Page 1 of 1**

Coordinator Instructions: Remind the patient that we need the following information to contact them concerning the Day 3, 7, 14, 21 and 28 Blood Draws (if the patient is discharged anytime before Day 28), 30 Days Post-Study Drug Discontinuation, and 2, 4, and 6 Month Post-Enrollment Follow-Up Telephone Call.

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*) Form Completed By (Initials): ☐☐☐ (*F M L*)

Section 1. Patient Information Date Form Completed: ☐☐ (*month*) ☐☐ (*day*) ☐☐ (*year*)

A. Name and Mailing Address

Last Name: _____ First Name: _____ Middle Initial: _____

Address: _____

City: _____ State: _____ Zip Code: ☐☐☐☐☐ - ☐☐☐☐

B. Phone Numbers

Home Phone: ☐☐☐ - ☐☐☐ - ☐☐☐☐ Best times to call: M-F _____ Sat/Sun _____

Work Phone: ☐☐☐ - ☐☐☐ - ☐☐☐☐ Best times to call: M-F _____ Sat/Sun _____

Cell Phone: ☐☐☐ - ☐☐☐ - ☐☐☐☐ Best times to call: M-F _____ Sat/Sun _____

C. Email Addresses

Primary email address: _____

Alternate email address: _____

Section 2. Alternate Contact

A. Name and Relationship to Patient

Last Name: _____ First Name: _____ Middle Initial: _____

Relationship to Patient: ☐ Parent ☐ Son/Daughter ☐ Sibling ☐ Other Relative ☐ Friend ☐ Employer ☐ Other *(specify)*: _____

B. Phone Numbers

Home Phone: ☐☐☐ - ☐☐☐ - ☐☐☐☐ Best times to call: M-F _____ Sat/Sun _____

Work Phone: ☐☐☐ - ☐☐☐ - ☐☐☐☐ Best times to call: M-F _____ Sat/Sun _____

Cell Phone: ☐☐☐ - ☐☐☐ - ☐☐☐☐ Best times to call: M-F _____ Sat/Sun _____

C. Email Address

Primary email address: _____

Fax this form to the Data Coordinating Center toll free at 866-477-1298.

PATIENT CONTACT LOG

TAB PAGE

Use this log to record all contacts, and attempted contacts, with the patient and/or patient's family or alternate contact.

This includes, but is not limited to, contact concerning the Day 3, 7, 14, 21 and 28 Blood Draws (if the patient is discharged anytime before Day 28), 30 Days Post-Study Drug Discontinuation, and 2, 4 and 6 Month Post-Enrollment Follow-Up Telephone Calls.

GLND **PATIENT CONTACT LOG - SITE COPY** **Page** ☐☐

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐
F M L

Use this log to record all contacts, and attempted contacts, with the patient and/or patient's family or alternate contact. Make copies of this page if needed (5 pages are provided).

Reason Codes: 1=Scheduled Visit 2=Missed Visit 3=Scheduled Call 4=Locate Patient 5=Other

Contact Codes: 1=Mail 2=Call to Patient 3=Call from Patient 4=Email 5=Other

Outcome Codes: 1=Successful contact 2=Spoke with other 3=Answering machine 4=Busy 5=No answer 6=Disconnected 7=Incorrect Information 8=Other

Day of Week	Date	Time	Contacter Initials	Reason Code	Contact Code	Outcome Code	Contact Point (phone number, address, etc.)	Comments

GLND **PATIENT CONTACT LOG - SITE COPY** **Page** ☐☐

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐
F M L

Use this log to record all contacts, and attempted contacts, with the patient and/or patient's family or alternate contact. Make copies of this page if needed (5 pages are provided).

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Contact Codes: 1=Mail 2=Call to Patient 3=Call from Patient 4=Email 5=Other

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Day of Week	Date	Time	Contacter Initials	Reason Code	Contact Code	Outcome Code	Contact Point (phone number, address, etc.)	Comments

GLND **PATIENT CONTACT LOG - SITE COPY** **Page** ☐☐

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐
F M L

Use this log to record all contacts, and attempted contacts, with the patient and/or patient's family or alternate contact. Make copies of this page if needed (5 pages are provided).

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Day of Week	Date	Time	Contacter Initials	Reason Code	Contact Code	Outcome Code	Contact Point (phone number, address, etc.)	Comments

GLND **PATIENT CONTACT LOG - SITE COPY** **Page** ☐☐

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐
F M L

Use this log to record all contacts, and attempted contacts, with the patient and/or patient's family or alternate contact. Make copies of this page if needed (5 pages are provided).

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Day of Week	Date	Time	Contacter Initials	Reason Code	Contact Code	Outcome Code	Contact Point (phone number, address, etc.)	Comments

GLND **PATIENT CONTACT LOG - SITE COPY** **Page** ☐☐

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐
F M L

Use this log to record all contacts, and attempted contacts, with the patient and/or patient's family or alternate contact. Make copies of this page if needed (5 pages are provided).

Reason Codes: 1=Scheduled Visit 2=Missed Visit 3=Scheduled Call 4=Locate Patient 5=Other

Contact Codes: 1=Mail 2=Call to Patient 3=Call from Patient 4=Email 5=Other

Outcome Codes: 1=Successful contact 2=Spoke with other 3=Answering machine 4=Busy 5=No answer 6=Disconnected 7=Incorrect Information 8=Other

Day of Week	Date	Time	Contacter Initials	Reason Code	Contact Code	Outcome Code	Contact Point (phone number, address, etc.)	Comments

DEMOGRAPHICS/ HISTORY FORM

TAB PAGE

DataFax #012 Plate #009 Visit #001

GLND **DEMOGRAPHICS / HISTORY FORM** **Page 1 of 2**

Note: This form must be completed the day the study drug is started.

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*) Form Completed By (Initials): ☐☐☐ (*F M L*)

Date Form Completed: ☐☐ (*month*) ☐☐ (*day*) ☐☐ (*year*)

Section 1. Demographics

1. Gender: ☐ Male ☐ Female

2. Date of birth: ☐☐ (*month*) ☐☐ (*day*) ☐☐ (*year*)

3. Is the patient Hispanic? ☐ No ☐ Yes

4. Race *(mark one):*
   - ☐ American Indian / Alaskan Native
   - ☐ Asian
   - ☐ Black or African American
   - ☐ Native Hawaiian or Other Pacific Islander
   - ☐ White
   - ☐ More than one race
   - ☐ Other *(specify):* _____

Section 2. Medical History

1. Date of initial hospitalization: ☐☐ (*month*) ☐☐ (*day*) ☐☐ (*year*)

2. Date of operation: ☐☐ (*month*) ☐☐ (*day*) ☐☐ (*year*)

3. Days in SICU prior to entry: ☐☐ days

4. Days of PN prior to entry: ☐☐ days

5. Pre-operative weight of individual: ☐☐☐ kg *NOTE: This weight should be taken from the anesthesia chart.*

6. Pre-operative height of individual: ☐☐☐.☐ cm

7. IBW of individual at admission: ☐☐☐.☐ kg

8. Percentage of body weight loss: Past 2 months: ☐☐ % Past 6 months: ☐☐ %

DataFax #012 Plate #010 Visit #001

GLND **DEMOGRAPHICS / HISTORY FORM**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*)

Section 3. Baseline Medical Information

1. Primary diagnosis *(mark 'X' one of the following):*

- ☐ CAD
- ☐ CHF
- ☐ Valve malfunction
- ☐ Intestinal trauma
- ☐ Intestinal ischemia
- ☐ Inflammatory bowel disease
- ☐ Benign intestinal tumors
- ☐ Intestinal perforation
- ☐ Intestinal fistula / stricture / adhesion
- ☐ Diverticulitis
- ☐ Vascular stenosis
- ☐ Vascular aneurysm
- ☐ Other *(specify):* _____

2. Subjective Global Assessment of underlying nutritional status at baseline *(mark 'X' one of the following):*

- ☐ No malnutrition
- ☐ Mild to moderate malnutrition
- ☐ Severe malnutrition

3. White blood cell count: ☐☐☐.☐ $10^3/\mu L$

4. Is Acute Respiratory Distress Syndrome present at baseline (fractional PaO2/FIO2 ratio of < 200 regardless of positive end-expiratory pressure; presence of bilateral infiltration on frontal chest x-rays; and pulmonary artery wedge pressure at ≤ 18 mmHg when measured, or no clinical evidence of left atrial hypertension)? ☐ No ☐ Yes

5. Is the patient on mechanical ventilation at baseline? ☐ No ☐ Yes

6. Is the patient on an intra-aortic balloon pump at baseline? ☐ No ☐ Yes

7. Has the patient exhibited evidence of post-operative nosocomial infection(s) prior to or at baseline? ☐ No ☐ Yes

If yes, make sure the infections log is updated, and the appropriate forms are completed and faxed to the data center.

Fax this form to the Data Coordinating Center toll free at 866-477-1298.

PN ORDER CALCULATION FORMS

TAB PAGE

DataFax #012 Plate #011 Visit #001

GLND **PN CALORIE AND MACRONUTRIENT COMPOSITION**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (F M L) Form Completed By (Initials): ☐☐☐ (F M L)

Date Form Completed: ☐☐ (month) ☐☐ (day) ☐☐ (year)

Use the following form to calculate the PN order. Instructions are provided for instances where a value needs to be carried to another place on the form.

Section 1. Total Calorie and Protein Calculations

☐☐☐☐ (1.A) x 1.3 = ☐☐☐☐ (1.B) − ☐☐☐☐ (1.C) = ☐☐☐☐ (1.D)

1.A Basal energy expenditure (BEE) by Harris-Benedict equation (kcal/day)

1.B Total kcal/day goal

1.C Total EN (kcal/day)

1.D Total PN (kcal/day) ***(insert value in item 2.A below)***

☐☐☐.☐ (1.E) x 1.5 g protein/kg/day = ☐☐☐ (1.F)

1.E Body weight in kg (actual or adjusted)

1.F Total protein (g/day) ***(insert value in item 1.G next line)***

☐☐☐ (1.G) − ☐☐☐ (1.H) = ☐☐☐ (1.I) x 4 kcal/g = ☐☐☐ (1.J)

1.G Total protein (g/day)

1.H Total EN protein (g/day)

1.I Total PN amino acid (g/day) ***(insert value in items 1.A, 2.A, & 3.A of PN Amino Acid Composition Form)***

1.J PN amino acid (kcal/day) ***(insert value in item 2.B next line)***

Section 2. Dextrose Calculations

☐☐☐☐ (2.A) − ☐☐☐ (2.B) = ☐☐☐☐ (2.C) x 0.7 = ☐☐☐☐ (2.D)

2.A Total PN (kcal/day)

2.B PN amino acid (kcal/day)

2.C Non-amino acid (kcal/day) ***(insert value in item 3.A next page)***

2.D Total IV dextrose from all sources (kcal/day) ***(insert value in item 2.E next line)***

☐☐☐☐ (2.E) ÷ 3.4 kcal/g = ☐☐☐ (2.F) − ☐☐☐ (2.G) = ☐☐☐ (2.H)

2.E Total IV dextrose from all sources (kcal/day)

2.F Total IV dextrose (g/day)

2.G Dextrose from IV fluids (g/day)

2.H PN dextrose (g/day) ***(insert value in item 2.I next line)***

☐☐☐ (2.I) ÷ ☐☐☐☐ (2.J) = ☐.☐☐☐ (2.K) x 100 = ☐☐.☐ (2.L) x 10 = ☐☐☐.☐ (2.M)

2.I PN dextrose (g/day)

2.J PN volume goal (mL/day) ***(insert value in items 4.C next page; also 1.C, 2.D, & 3.C of PN Amino Acid Composition Form)***

2.K

2.L PN dextrose concentration (%)

2.M PN DEXTROSE (g/L)

DataFax #012 Plate #012 Visit #001

GLND **PN CALORIE AND MACRONUTRIENT COMPOSITION**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*)

Section 3. Lipids Calculations

Indicate whether the result is positive or negative

☐☐☐☐ x 0.3 = ☐☐☐☐ – ☐☐☐☐ = ☐ + / ☐ – ☐☐☐☐

3.A	3.B	3.C	3.D
Non-amino acid (kcal/day) ***(from 2.C page 1)***	Total IV lipid (kcal/day)	Propofol (kcal/day)	IV lipid (kcal/day)

3.E Is the IV lipid kcal/day value negative?

☐ No *(insert the IV lipid kcal/day value [from 3.D above] in item 5.A below and skip Section 4)*

☐ Yes *(insert the IV lipid kcal/day value [from 3.D above ignoring the negative sign] in item 4.A below, and recalculate the PN dextrose in Section 4; do not complete Section 5)*

Section 4. Dextrose Recalculations (if needed)

☐☐☐☐ ÷ 3.4 = ☐☐☐ ÷ ☐☐☐☐ = ☐.☐☐☐ x 100 = ☐☐.☐

4.A	4.B	4.C	4.D	4.E
IV lipid (kcal/day)	Dextrose Equivalent (g/day)	PN volume goal (mL/day) ***(same value as item 2.J page 1)***		Dextrose equivalent concentration (%) ***(insert value in item 4.G next line)***

☐☐.☐ – ☐☐.☐ = ☐☐.☐ x 10 = ☐☐☐

4.F	4.G	4.H	**4.I**
PN Dextrose concentration (%) ***(same value as item 2.L page 1)***	Dextrose equivalent concentration (%)	Final PN Dextrose concentration (%)	**FINAL PN DEXTROSE (g/L)**

NOTE: If Section 4 completed, skip Section 5 and continue to the PN Amino Acid Composition Form.

Section 5. Lipid Infusion (if needed)

Indicate the infusion hours and proceed with the calculations

☐☐☐☐ ÷ 2 kcal/mL = ☐☐☐☐ ÷ ☐ 10 hours / ☐ 12 hours = ☐☐☐

5.A	5.B	**5.C**
IV lipid (kcal/day)	20% Intralipid (mL)	**IV lipid (mL/hr)**

Fax this form to the Data Coordinating Center toll free at 866-477-1298.

DataFax #012 Plate #013 Visit #001

GLND **PN CALORIE AND MACRONUTRIENT COMPOSITION**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*)

Section 3. Lipids Calculations

Indicate whether the result is positive or negative

☐☐☐☐ **x** 0.3 **=** ☐☐☐☐ **–** ☐☐☐☐ **=** ☐ + / ☐ – ☐☐☐☐

3.A		3.B		3.C		3.D
Non-amino acid (kcal/day) ***(from 2.C page 1)***		Total IV lipid (kcal/day)		Propofol (kcal/day)		IV lipid (kcal/day)

3.E Is the IV lipid kcal/day value negative?

☐ No *(insert the IV lipid kcal/day value [from 3.D above] in item 5.A below and skip Section 4)*

☐ Yes *(insert the IV lipid kcal/day value [from 3.D above ignoring the negative sign] in item 4.A below, and recalculate the PN dextrose in Section 4; do not complete Section 5)*

Section 4. Dextrose Recalculations (if needed)

☐☐☐☐ **÷** 3.4 **=** ☐☐☐

4.A		4.B
IV lipid (kcal/day)		Dextrose Equivalent (g/day) ***(insert value in item 4.D below)***

☐☐☐ **–** ☐☐☐ **=** ☐☐☐

4.C		4.D		**4.E**
PN Dextrose (g/day) ***(same value as item 2.H page 1)***		Dextrose equivalent (g/day)		**Final PN Dextrose (g/day)**

NOTE: If Section 4 completed, skip Section 5 and continue to the PN Amino Acid Composition Form.

Section 5. Lipid Infusion (if needed)

Indicate the infusion hours and proceed with the calculations

☐☐☐☐ **÷** 2 kcal/mL **=** ☐☐☐☐ **÷** ☐ 10 hours / ☐ 12 hours **=** ☐☐☐

5.A		5.B		**5.C**
IV lipid (kcal/day)		20% Intralipid (mL)		**IV lipid (mL/hr)**

Fax this form to the Data Coordinating Center toll free at 866-477-1298.

DataFax #012 Plate #014 Visit #001

GLND **PN AMINO ACID COMPOSITION - 1st CALCULATION** **Page 1 of 1**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (F M L) Form Completed By (Initials): ☐☐☐ (F M L)

Date Form Completed: ☐☐ (month) ☐☐ (day) ☐☐ (year)

The following calculations apply to patients who are randomized to AG-PN or STD-PN. Please fill out the entire page.

NOTE: Refer to the PN Calorie and Macronutrient Composition Form item 1.I for the Total PN amino acid values (insert in items 1.A, 2.A and 3.A below), and item 2.J for PN volume goal values (insert in items 1.C, 2.D and 3.C below).

Section 1. AG-PN Calculations (Dipeptiven)

Determine the volume and final concentration of Dipeptiven (20% alanyl-GLN dipeptide solution) to add to the AG-PN.

☐☐☐ (1.A) x 0.34 = ☐☐.☐ (1.B) ÷ ☐☐☐☐ (1.C) = ☐.☐☐☐☐ (1.D)

1.A Total PN amino acid (g/day)

1.B 20% AG dipeptide (g/day)

1.C PN volume goal *(mL/day)*

1.D ***(insert value in item 1.E below)***

☐.☐☐☐☐ (1.E) x 100 = ☐.☐☐ (1.F) x 10 = ☐☐.☐ (**1.G**)

1.E ***(value from item 1.D above)***

1.F AG dipeptide in PN (%)

1.G AG dipeptide in PN (g/L)

Note: No more than 35 g/L or 3.5% of AG dipeptide (Dipeptiven) is to be added to PN daily. Increase PN volume as needed.

Section 2. AG-PN Calculations (Clinisol)

Determine the volume and final concentration of 15% Clinisol amino acid solution to add to the AG-PN.

☐☐☐ (2.A) – ☐☐.☐ (2.B) = ☐☐☐.☐ (2.C) ÷ ☐☐☐☐ (2.D) = ☐.☐☐☐☐ (2.E)

2.A Total PN amino acid (g/day)

2.B 20% AG dipeptide (g/day) ***(same value as item 1.B above)***

2.C 15% Clinisol (g/day)

2.D PN volume goal *(mL/day)*

2.E ***(insert value in item 2.F below)***

☐.☐☐☐☐ (2.F) x 100 = ☐.☐☐ (2.G) x 10 = ☐☐.☐ (**2.H**)

2.F ***(value from item 2.E above)***

2.G Clinisol in AG-PN (%)

2.H Clinisol in AG-PN (g/L)

Section 3. STD-PN Calculations (Clinisol)

Determine the volume and final concentration of 15% Clinisol amino acid solution to add to the STD-PN.

☐☐☐ (3.A) = ☐☐☐ (3.B) ÷ ☐☐☐☐ (3.C) = ☐.☐☐☐☐ (3.D)

3.A Total PN amino acid (g/day)

3.B Clinisol (g/day)

3.C PN volume goal *(mL/day)*

3.D ***(insert value in item 3.E below)***

☐.☐☐☐☐ (3.E) x 100 = ☐.☐☐ (3.F) x 10 = ☐☐.☐ (**3.G**)

3.E ***(value from item 3.D above)***

3.F Clinisol in STD-PN (%)

3.G Clinisol in STD-PN (g/L)

DataFax #012 Plate #015 Visit #001

GLND **DAY XX PLASMA & SERUM STORAGE FORM**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*) Form Completed By (Initials): ☐☐☐ (*F M L*)

Date Form Completed: ☐☐ (*month*) ☐☐ (*day*) ☐☐ (*year*)

Section 1. General Blood Draw Information

1. Date blood taken for storage: ☐☐ (*month*) ☐☐ (*day*) ☐☐ (*year*)

2. Time of blood draw *(24 hour clock)*: ☐☐ : ☐☐

3. Type of blood draw: ☐ Arterial ☐ Venous

Section 2. Blood Draw Sample Information

Blood samples must be stored in the volume indicated below. If the indicated blood volume is not drawn **or there is evidence of hemolysis**, redraw the sample, store it and provide the appropriate answer for the corresponding question. Answer 'No' only in situations where the blood cannot be redrawn; in such situations, also provide an explanation in the narrative section on the following page.

A. GSH & CyS Redox storage

Use 2 Yellow microfuge tubes

1.	GSH:	Has a plasma sample of exactly 0.2 mL been stored?	☐ Yes	☐ No	*(Attempt to redraw before answering 'No.')*
2.	CyS:	Has a plasma sample of exactly 0.2 mL been stored?	☐ Yes	☐ No	

B. Clinical Chemistries

Use 3 Green microfuge tubes

1.	Chem:	Has a plasma sample of ≥ 0.5 mL been stored?	☐ Yes	☐ No	*(Attempt to redraw before answering 'No.')*
2.	CRP:	Has a plasma sample of ≥ 0.5 mL been stored?	☐ Yes	☐ No	
3.	xtra:	Has a plasma sample of ≥ 0.5 mL been stored?	☐ Yes	☐ No	

C. Glutamine & Glutamate

Use 3 Blue microfuge tubes

1.	GLN:	Has a plasma sample of ≥ 0.5 mL been stored?	☐ Yes	☐ No	*(Attempt to redraw before answering 'No.')*
2.	GLU:	Has a plasma sample of ≥ 0.5 mL been stored?	☐ Yes	☐ No	
3.	xtra:	Has a plasma sample of ≥ 0.5 mL been stored?	☐ Yes	☐ No	

D. LPS & Flagellin

Use 3 Orange microfuge tubes

1.	FLAG:	Has a serum sample of ≥ 0.5 mL been stored?	☐ Yes	☐ No	*(Attempt to redraw before answering 'No.')*
2.	LPS:	Has a serum sample of ≥ 0.5 mL been stored?	☐ Yes	☐ No	
3.	xtra:	Has a serum sample of ≥ 0.5 mL been stored?	☐ Yes	☐ No	

DataFax #012 Plate #016 Visit #001

GLND **DAY XX PLASMA & SERUM STORAGE FORM**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*)

Section 2. Blood Draw Sample Information (continued)

E. Cytokines

Use 3 Lavender microfuge tubes

1.	CYTO1:	Has a serum sample of ≥ 0.5 mL been stored?	☐ Yes	☐ No	
2.	CYTO2:	Has a serum sample of ≥ 0.5 mL been stored?	☐ Yes	☐ No	*(Attempt to redraw before answering 'No.')*
3.	xtra:	Has a serum sample of ≥ 0.5 mL been stored?	☐ Yes	☐ No	

F. Heat-shock proteins

Use 3 Red microfuge tubes

1.	HSP70:	Has a serum sample of ≥ 0.5 mL been stored?	☐ Yes	☐ No	
2.	HSP27:	Has a serum sample of ≥ 0.5 mL been stored?	☐ Yes	☐ No	*(Attempt to redraw before answering 'No.')*
3.	xtra:	Has a serum sample of ≥ 0.5 mL been stored?	☐ Yes	☐ No	

G. Flagellin/LPS antibody

Use 3 Amber microfuge tubes

1.	Anti-FLAG:	Has a serum sample of ≥ 0.5 mL been stored?	☐ Yes	☐ No	
2.	Anti-LPS:	Has a serum sample of ≥ 0.5 mL been stored?	☐ Yes	☐ No	*(Attempt to redraw before answering 'No.')*
3.	xtra:	Has a serum sample of ≥ 0.5 mL been stored?	☐ Yes	☐ No	

Section 3. Narrative

Print legibly any comments pertaining to an unsuccessful blood draw, where the appropriate blood volume was not stored.

VALIDATION: Narrative provided? ☐ No ☐ Yes

Fax this form to the Data Coordinating Center toll free at 866-477-1298.

CONCOMITANT MEDICATIONS FORM

TAB PAGE

DataFax #012 Plate #017 Visit #001

GLND CONCOMITANT MEDICATIONS FORM

Complete this form initially at patient baseline. Each time that there is a change in the patient's medication regimen, make the appropriate changes to this form and re-fax this form to the Data Coordinating Center. If a patient stops a medication and restarts it, the restart should be a new entry on the form. If the patient starts a new medication and all of the lines on this page have been completed, go on to the next page. Only pages with medications indicated should be faxed or re-faxed to the Data Coordinating Center.

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*) Form Completed By (Initials): ☐☐☐ (*F M L*)

Medication Codes

01 Activated Protein C (Xygris®)	04 Corticosteroids	07 Paralytics
02 Antibiotics - Antibacterial Agents **	05 H_2 Blockers or Proton Pump Inhibitor	08 Vasopressors *
03 Antibiotics - Antifungal Agents **	06 Hypoglycemics	

** Stop Date is defined as the date the medication is permanently discontinued.*

*** If antibiotics (codes 02 or 03) indicate the total daily dose in milligrams (mg); otherwise leave column blank.*

Medication	**Med. Code**	**Total Daily Dose** *(convert g to mg)*	**Start Date** *(mm/dd/yy)*	**Stop Date** *(mm/dd/yy)*

DataFax #012 Plate #018 Visit #001

GLND **CONCOMITANT MEDICATIONS FORM** **Page 2 of 5**

Complete this form initially at patient baseline. Each time that there is a change in the patient's medication regimen, make the appropriate changes to this form and re-fax this form to the Data Coordinating Center. If a patient stops a medication and restarts it, the restart should be a new entry on the form. If the patient starts a new medication and all of the lines on this page have been completed, go on to the next page. Only pages with medications indicated should be faxed or re-faxed to the Data Coordinating Center.

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*) Form Completed By (Initials): ☐☐☐ (*F M L*)

Medication Codes

01 Activated Protein C (Xygris®)	04 Corticosteroids	07 Paralytics
02 Antibiotics - Antibacterial Agents **	05 H_2 Blockers or Proton Pump Inhibitor	08 Vasopressors *
03 Antibiotics - Antifungal Agents **	06 Hypoglycemics	

** Stop Date is defined as the date the medication is permanently discontinued.*

*** If antibiotics (codes 02 or 03) indicate the total daily dose in milligrams (mg); otherwise leave column blank.*

Medication	Med. Code	Total Daily Dose *(convert g to mg)*	Start Date *(mm/dd/yy)*	Stop Date *(mm/dd/yy)*

Fax this form to the Data Coordinating Center toll free at 866-477-1298.

DataFax #012 Plate #019 Visit #001

GLND **CONCOMITANT MEDICATIONS FORM**

Complete this form initially at patient baseline. Each time that there is a change in the patient's medication regimen, make the appropriate changes to this form and re-fax this form to the Data Coordinating Center. If a patient stops a medication and restarts it, the restart should be a new entry on the form. If the patient starts a new medication and all of the lines on this page have been completed, go on to the next page. Only pages with medications indicated should be faxed or re-faxed to the Data Coordinating Center.

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*) Form Completed By (Initials): ☐☐☐ (*F M L*)

Medication Codes

01 Activated Protein C (Xygris®)
02 Antibiotics - Antibacterial Agents **
03 Antibiotics - Antifungal Agents **
04 Corticosteroids
05 H_2 Blockers or Proton Pump Inhibitor
06 Hypoglycemics
07 Paralytics
08 Vasopressors *

** Stop Date is defined as the date the medication is permanently discontinued.*

*** If antibiotics (codes 02 or 03) indicate the total daily dose in milligrams (mg); otherwise leave column blank.*

Medication	Med. Code	Total Daily Dose (convert g to mg)	Start Date (mm/dd/yy)	Stop Date (mm/dd/yy)

DataFax #012 Plate #020 Visit #001

GLND **CONCOMITANT MEDICATIONS FORM**

Complete this form initially at patient baseline. Each time that there is a change in the patient's medication regimen, make the appropriate changes to this form and re-fax this form to the Data Coordinating Center. If a patient stops a medication and restarts it, the restart should be a new entry on the form. If the patient starts a new medication and all of the lines on this page have been completed, go on to the next page. Only pages with medications indicated should be faxed or re-faxed to the Data Coordinating Center.

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*) Form Completed By (Initials): ☐☐☐ (*F M L*)

Medication Codes

01 Activated Protein C (Xygris®)	04 Corticosteroids	07 Paralytics
02 Antibiotics - Antibacterial Agents **	05 H_2 Blockers or Proton Pump Inhibitor	08 Vasopressors *
03 Antibiotics - Antifungal Agents **	06 Hypoglycemics	

** Stop Date is defined as the date the medication is permanently discontinued.*

*** If antibiotics (codes 02 or 03) indicate the total daily dose in milligrams (mg); otherwise leave column blank.*

Medication	**Med. Code**	**Total Daily Dose** *(convert g to mg)*	**Start Date** *(mm/dd/yy)*	**Stop Date** *(mm/dd/yy)*

Fax this form to the Data Coordinating Center toll free at 866-477-1298.

DataFax #012 Plate #021 Visit #001

GLND **CONCOMITANT MEDICATIONS FORM**

Complete this form initially at patient baseline. Each time that there is a change in the patient's medication regimen, make the appropriate changes to this form and re-fax this form to the Data Coordinating Center. If a patient stops a medication and restarts it, the restart should be a new entry on the form. If the patient starts a new medication and all of the lines on this page have been completed, go on to the next page. Only pages with medications indicated should be faxed or re-faxed to the Data Coordinating Center.

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*) Form Completed By (Initials): ☐☐☐ (*F M L*)

Medication Codes

01 Activated Protein C (Xygris®)
02 Antibiotics - Antibacterial Agents **
03 Antibiotics - Antifungal Agents **
04 Corticosteroids
05 H_2 Blockers or Proton Pump Inhibitor
06 Hypoglycemics
07 Paralytics
08 Vasopressors *

** Stop Date is defined as the date the medication is permanently discontinued.*

*** If antibiotics (codes 02 or 03) indicate the total daily dose in milligrams (mg); otherwise leave column blank.*

Medication	Med. Code	Total Daily Dose *(convert g to mg)*	Start Date *(mm/dd/yy)*	Stop Date *(mm/dd/yy)*

SCHEDULED FORMS

This part of the binder contains all the follow-up and blood draw forms.

DAY 3 PLASMA & SERUM STORAGE FORM

TAB PAGE

DataFax #012 Plate #015 Visit #002

DataFax #012 Plate #016 Visit #002

DAY 3 FOLLOW-UP FORM

TAB PAGE

DataFax #012 Plate #022 Visit #002

GLND **DAY 3 FOLLOW-UP FORM**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (F M L) Form Completed By (Initials): ☐☐☐ (F M L)

Date Form Completed: ☐☐ (month) ☐☐ (day) ☐☐ (year)

Section 1. Study Drug Information

1. Date and time study drug started: ☐☐ (month) ☐☐ (day) ☐☐ (year) ☐☐:☐☐ *(24 hour clock)*

2. Has the patient received enteral nutrition since enrollment? ☐ No ☐ Yes → If yes, indicate: No. of days: ☐
   Mean daily kcal: ☐☐☐☐

3. Has the patient received parenteral nutrition since enrollment? ☐ No ☐ Yes → If yes, indicate: No. of days: ☐
   Mean daily kcal: ☐☐☐☐

Note: Day 1 officially begins at your institution's PN hang time on the date the study drug is started. A day is defined as the 24-hour period beginning at your institution's PN hang time and ending the following day. Please use use this definition when filling out all of the follow-up forms, as appropriate.

Section 2. Entry Nutritional Goals

Obtain the entry nutritional goals from the person who wrote the PN order and enter those values in the spaces provided below. Both items should indicate the total per day.

1. Total protein/amino acid: ☐☐☐ g

2. Total kcal: ☐☐☐☐ kcal

DataFax #012 Plate #023 Visit #002

GLND **DAY 3 FOLLOW-UP FORM**

A day is defined as the 24-hour period beginning at your institution's PN hang time and ending the following day. Please use this definition when filling out the items in this section, as appropriate.

Only complete this page of the form if the patient has been hospitalized for at least some portion of this day. Skip to Section 4 on page 5 of this form if the patient was not hospitalized on this day.

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*)

Section 3: Day 1

A. Actual Nutritional Intake

Provide the daily parenteral and enteral nutritional intake. All items should indicate the total per day. *(Enter zeros if the patient did not receive the indicated item.)*

1) Total infused PN volume: ☐☐☐☐ mL
2) PN amino acid (AA): ☐☐☐ g
3) PN kcal: ☐☐☐☐ kcal
4) Tube feeding protein: ☐☐☐ g
5) Tube feeding kcal: ☐☐☐☐ kcal
6) Oral food protein: ☐☐☐ g
7) Oral food kcal: ☐☐☐☐ kcal
8) IV fluids kcal: ☐☐☐☐ kcal
9) Propofol kcal: ☐☐☐☐ kcal
10) Total protein/amino acid: ☐☐☐ g
11) Total kcal: ☐☐☐☐ kcal
12) Total Insulin administered: ☐☐☐☐ units

B. Blood Glucose

Provide the serial blood glucose and time of the measurement for each of the three time intervals specified. Use the value first recorded within the time interval if there is more than one value available. If there is no value available within the time interval, provide the value closest to the time interval. *(Enter '999' if a blood glucose value is not available.)*

1) 2200 - 2400: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*
2) 0500 - 0700: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*
3) 1400 - 1600: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*

C. SOFA SCORE

Provide the SOFA score for each category, and the SOFA score total. *(Enter zeros if a SOFA Score is not available.)*

1) Respiration: ☐ 3) Liver: ☐ 5) Cen. Nervous System: ☐
2) Coagulation: ☐ 4) Cardiovascular: ☐ 6) Renal: ☐
→ **TOTAL** *(add 1-6)*: ☐☐

D. NOTES ON CLINICAL COURSE

Print legibly any comments pertaining to clinical outcomes, fluid status and/or enteral or parenteral nutrition administration.

VALIDATION: Narrative provided? ☐ No ☐ Yes

DataFax #012 Plate #024 Visit #002

GLND **DAY 3 FOLLOW-UP FORM**

A day is defined as the 24-hour period beginning at your institution's PN hang time and ending the following day. Please use this definition when filling out the items in this section, as appropriate.

Only complete this page of the form if the patient has been hospitalized for at least some portion of this day. Skip to Section 4 on page 5 of this form if the patient was not hospitalized on this day.

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*)

Section 3: Day 2

A. Actual Nutritional Intake

Provide the daily parenteral and enteral nutritional intake. All items should indicate the total per day. *(Enter zeros if the patient did not receive the indicated item.)*

1) Total infused PN volume: ☐☐☐☐ mL
2) PN amino acid (AA): ☐☐☐ g
3) PN kcal: ☐☐☐☐ kcal
4) Tube feeding protein: ☐☐☐ g
5) Tube feeding kcal: ☐☐☐☐ kcal
6) Oral food protein: ☐☐☐ g
7) Oral food kcal: ☐☐☐☐ kcal
8) IV fluids kcal: ☐☐☐☐ kcal
9) Propofol kcal: ☐☐☐☐ kcal
10) Total protein/amino acid: ☐☐☐ g
11) Total kcal: ☐☐☐☐ kcal
12) Total Insulin administered: ☐☐☐☐ units

B. Blood Glucose

Provide the serial blood glucose and time of the measurement for each of the three time intervals specified. Use the value first recorded within the time interval if there is more than one value available. If there is no value available within the time interval, provide the value closest to the time interval. *(Enter '999' if a blood glucose value is not available.)*

1) 2200 - 2400: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*
2) 0500 - 0700: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*
3) 1400 - 1600: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*

C. SOFA SCORE

Provide the SOFA score for each category, and the SOFA score total. *(Enter zeros if a SOFA Score is not available.)*

1) Respiration: ☐ 3) Liver: ☐ 5) Cen. Nervous System: ☐
2) Coagulation: ☐ 4) Cardiovascular: ☐ 6) Renal: ☐
→ **TOTAL** *(add 1-6)*: ☐☐

D. NOTES ON CLINICAL COURSE

Print legibly any comments pertaining to clinical outcomes, fluid status and/or enteral or parenteral nutrition administration.

VALIDATION: Narrative provided? ☐ No ☐ Yes

DataFax #012 Plate #025 Visit #002

GLND **DAY 3 FOLLOW-UP FORM**

A day is defined as the 24-hour period beginning at your institution's PN hang time and ending the following day. Please use this definition when filling out the items in this section, as appropriate.

Only complete this page of the form if the patient has been hospitalized for at least some portion of this day. Skip to Section 4 on page 5 of this form if the patient was not hospitalized on this day.

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*)

Section 3: Day 3

A. Actual Nutritional Intake

Provide the daily parenteral and enteral nutritional intake. All items should indicate the total per day. *(Enter zeros if the patient did not receive the indicated item.)*

1) Total infused PN volume: ☐☐☐☐ mL
2) PN amino acid (AA): ☐☐☐ g
3) PN kcal: ☐☐☐☐ kcal
4) Tube feeding protein: ☐☐☐ g
5) Tube feeding kcal: ☐☐☐☐ kcal
6) Oral food protein: ☐☐☐ g
7) Oral food kcal: ☐☐☐☐ kcal
8) IV fluids kcal: ☐☐☐☐ kcal
9) Propofol kcal: ☐☐☐☐ kcal
10) Total protein/amino acid: ☐☐☐ g
11) Total kcal: ☐☐☐☐ kcal
12) Total Insulin administered: ☐☐☐☐ units

B. Blood Glucose

Provide the serial blood glucose and time of the measurement for each of the three time intervals specified. Use the value first recorded within the time interval if there is more than one value available. If there is no value available within the time interval, provide the value closest to the time interval. *(Enter '999' if a blood glucose value is not available.)*

1) 2200 - 2400: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*
2) 0500 - 0700: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*
3) 1400 - 1600: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*

C. SOFA SCORE

Provide the SOFA score for each category, and the SOFA score total. *(Enter zeros if a SOFA Score is not available.)*

1) Respiration: ☐ 3) Liver: ☐ 5) Cen. Nervous System: ☐
2) Coagulation: ☐ 4) Cardiovascular: ☐ 6) Renal: ☐
→ **TOTAL** *(add 1-6)*: ☐☐

D. NOTES ON CLINICAL COURSE

Print legibly any comments pertaining to clinical outcomes, fluid status and/or enteral or parenteral nutrition administration.

VALIDATION: Narrative provided? ☐ No ☐ Yes

DataFax #012 Plate #026 Visit #002

GLND **DAY 3 FOLLOW-UP FORM**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*)

Section 4. Hospital Information

1. Is the patient still hospitalized? ☐ Yes ☐ No → If no, date released from hospital *(skip to Section 6 after completing the date)*: ☐☐ *month* ☐☐ *day* ☐☐ *year*

2. Is the patient still in the SICU? ☐ Yes ☐ No → If no, date released from SICU *(skip to 4.5 after completing the date)*: ☐☐ *month* ☐☐ *day* ☐☐ *year*

3. Is Acute Respiratory Distress Syndrome present (fractional PaO_2/FIO_2 ratio of <200 regardless of positive end-expiratory pressure; presence of bilateral infiltration on frontal chest x-rays; and pulmonary artery wedge pressure at ≤ 18 mmHg when measured, or no clinical evidence of left atrial hypertension)? ☐ Yes ☐ No
If new, date first present: ☐☐ *month* ☐☐ *day* ☐☐ *year*

4. Is the patient on mechanical ventilation? ☐ Yes ☐ No → If removed from ventilation since baseline, date removed: ☐☐ *month* ☐☐ *day* ☐☐ *year*

5. Is the patient receiving the study PN? ☐ Yes ☐ No → If no, time and date the study PN stopped: ☐☐:☐☐ *(24 hour clock)*
☐☐ *month* ☐☐ *day* ☐☐ *year*

6. Provide the patient's current body weight *(enter '999.9' if not available)*: ☐☐☐.☐ kg
Date patient weighed: ☐☐ *month* ☐☐ *day* ☐☐ *year*

Section 5. New Nosocomial Infections

1. Has the patient exhibited evidence of new nosocomial infection(s) since baseline? ☐ Yes ☐ No

If yes, make sure the infections log is updated, and the appropriate forms are completed and faxed to the data center.

Section 6. Adverse Events

1. Has the patient experienced any adverse events since baseline? ☐ Yes ☐ No
2. If yes to #1, was the adverse event serious? ☐ Yes ☐ No

If the patient has experienced an adverse event, make sure the AE Log Worksheet is current and that the appropriate AE or SAE Case Report Form is completed and faxed to the data center.

Section 7. Concomitant Medications

1. Has the patient had a change in concomitant medications since baseline? ☐ Yes ☐ No
2. If yes to #1, update the Concomitant Medications Form. Updates include new medications, changes in antibiotic dose and the stop of previously indicated medications since baseline. You do not need to repeat previously reported medications if there has not been a change.

☐ Mark this box when the Concomitant Medications Form has been updated and faxed in.

REMINDER: Day 3, 7, 14, 21 and 28 Blood Draws must take place REGARDLESS of when the patient is discharged.

Fax this form to the Data Coordinating Center toll free at 866-477-1298.

DAY 7 PLASMA & SERUM STORAGE FORM

TAB PAGE

DataFax #012 Plate #015 Visit #003

DataFax #012 Plate #016 Visit #003

DAY 7 FOLLOW-UP FORM

TAB PAGE

DataFax #012 Plate #027 Visit #003

GLND **DAY 7 FOLLOW-UP FORM**

A day is defined as the 24-hour period beginning at your institution's PN hang time and ending the following day. Please use this definition when filling out the items in this section, as appropriate.

Only complete this form if the patient has been hospitalized for at least some portion of Day 4, 5, 6 or 7.

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (F M L) Form Completed By (Initials): ☐☐☐ (F M L)

Section 1: Day 4 Date Form Completed: ☐☐ (month) ☐☐ (day) ☐☐ (year)

A. Actual Nutritional Intake

Provide the daily parenteral and enteral nutritional intake. All items should indicate the total per day. *(Enter zeros if the patient did not receive the indicated item.)*

1) Total infused PN volume: ☐☐☐☐ mL
2) PN amino acid (AA): ☐☐☐ g
3) PN kcal: ☐☐☐☐ kcal
4) Tube feeding protein: ☐☐☐ g
5) Tube feeding kcal: ☐☐☐☐ kcal
6) Oral food protein: ☐☐☐ g
7) Oral food kcal: ☐☐☐☐ kcal
8) IV fluids kcal: ☐☐☐☐ kcal
9) Propofol kcal: ☐☐☐☐ kcal
10) Total protein/amino acid: ☐☐☐ g
11) Total kcal: ☐☐☐☐ kcal
12) Total Insulin administered: ☐☐☐☐ units

B. Blood Glucose

Provide the serial blood glucose and time of the measurement for each of the three time intervals specified. Use the value first recorded within the time interval if there is more than one value available. If there is no value available within the time interval, provide the value closest to the time interval. *(Enter '999' if a blood glucose value is not available.)*

1) 2200 - 2400: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*
2) 0500 - 0700: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*
3) 1400 - 1600: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*

C. SOFA SCORE

Provide the SOFA score for each category, and the SOFA score total. *(Enter zeros if a SOFA Score is not available.)*

1) Respiration: ☐ 3) Liver: ☐ 5) Cen. Nervous System: ☐
2) Coagulation: ☐ 4) Cardiovascular: ☐ 6) Renal: ☐
→ **TOTAL** *(add 1-6)*: ☐☐

D. NOTES ON CLINICAL COURSE

Print legibly any comments pertaining to clinical outcomes, fluid status and/or enteral or parenteral nutrition administration.

VALIDATION: Narrative provided? ☐ No ☐ Yes

DataFax #012 Plate #028 Visit #003

GLND **DAY 7 FOLLOW-UP FORM**

A day is defined as the 24-hour period beginning at your institution's PN hang time and ending the following day. Please use this definition when filling out the items in this section, as appropriate.

Only complete this page of the form if the patient has been hospitalized for at least some portion of this day. Skip to Section 2 on page 5 of this form if the patient was not hospitalized on this day.

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*)

Section 1: Day 5

A. Actual Nutritional Intake

Provide the daily parenteral and enteral nutritional intake. All items should indicate the total per day. *(Enter zeros if the patient did not receive the indicated item.)*

1) Total infused PN volume: ☐☐☐☐ mL
2) PN amino acid (AA): ☐☐☐ g
3) PN kcal: ☐☐☐☐ kcal
4) Tube feeding protein: ☐☐☐ g
5) Tube feeding kcal: ☐☐☐☐ kcal
6) Oral food protein: ☐☐☐ g
7) Oral food kcal: ☐☐☐☐ kcal
8) IV fluids kcal: ☐☐☐☐ kcal
9) Propofol kcal: ☐☐☐☐ kcal
10) Total protein/amino acid: ☐☐☐ g
11) Total kcal: ☐☐☐☐ kcal
12) Total Insulin administered: ☐☐☐☐ units

B. Blood Glucose

Provide the serial blood glucose and time of the measurement for each of the three time intervals specified. Use the value first recorded within the time interval if there is more than one value available. If there is no value available within the time interval, provide the value closest to the time interval. *(Enter '999' if a blood glucose value is not available.)*

1) 2200 - 2400: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*
2) 0500 - 0700: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*
3) 1400 - 1600: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*

C. SOFA SCORE

Provide the SOFA score for each category, and the SOFA score total. *(Enter zeros if a SOFA Score is not available.)*

1) Respiration: ☐ 3) Liver: ☐ 5) Cen. Nervous System: ☐
2) Coagulation: ☐ 4) Cardiovascular: ☐ 6) Renal: ☐

→ **TOTAL** *(add 1-6)*: ☐☐

D. NOTES ON CLINICAL COURSE

Print legibly any comments pertaining to clinical outcomes, fluid status and/or enteral or parenteral nutrition administration.

VALIDATION: Narrative provided? ☐ No ☐ Yes

DataFax #012 Plate #029 Visit #003

GLND **DAY 7 FOLLOW-UP FORM**

A day is defined as the 24-hour period beginning at your institution's PN hang time and ending the following day. Please use this definition when filling out the items in this section, as appropriate.

Only complete this page of the form if the patient has been hospitalized for at least some portion of this day. Skip to Section 2 on page 5 of this form if the patient was not hospitalized on this day.

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*)

Section 1: Day 6

A. Actual Nutritional Intake

Provide the daily parenteral and enteral nutritional intake. All items should indicate the total per day. *(Enter zeros if the patient did not receive the indicated item.)*

1) Total infused PN volume: ☐☐☐☐ mL
2) PN amino acid (AA): ☐☐☐ g
3) PN kcal: ☐☐☐☐ kcal
4) Tube feeding protein: ☐☐☐ g
5) Tube feeding kcal: ☐☐☐☐ kcal
6) Oral food protein: ☐☐☐ g
7) Oral food kcal: ☐☐☐☐ kcal
8) IV fluids kcal: ☐☐☐☐ kcal
9) Propofol kcal: ☐☐☐☐ kcal
10) Total protein/amino acid: ☐☐☐ g
11) Total kcal: ☐☐☐☐ kcal
12) Total Insulin administered: ☐☐☐☐ units

B. Blood Glucose

Provide the serial blood glucose and time of the measurement for each of the three time intervals specified. Use the value first recorded within the time interval if there is more than one value available. If there is no value available within the time interval, provide the value closest to the time interval. *(Enter '999' if a blood glucose value is not available.)*

1) 2200 - 2400: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*
2) 0500 - 0700: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*
3) 1400 - 1600: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*

C. SOFA SCORE

Provide the SOFA score for each category, and the SOFA score total. *(Enter zeros if a SOFA Score is not available.)*

1) Respiration: ☐ 3) Liver: ☐ 5) Cen. Nervous System: ☐
2) Coagulation: ☐ 4) Cardiovascular: ☐ 6) Renal: ☐
→ **TOTAL** *(add 1-6)*: ☐☐

D. NOTES ON CLINICAL COURSE

Print legibly any comments pertaining to clinical outcomes, fluid status and/or enteral or parenteral nutrition administration.

VALIDATION: Narrative provided? ☐ No ☐ Yes

DataFax #012 Plate #030 Visit #003

GLND **DAY 7 FOLLOW-UP FORM**

A day is defined as the 24-hour period beginning at your institution's PN hang time and ending the following day. Please use this definition when filling out the items in this section, as appropriate.

Only complete this page of the form if the patient has been hospitalized for at least some portion of this day. Skip to Section 2 on page 5 of this form if the patient was not hospitalized on this day.

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*)

Section 1: Day 7

A. Actual Nutritional Intake

Provide the daily parenteral and enteral nutritional intake. All items should indicate the total per day. *(Enter zeros if the patient did not receive the indicated item.)*

1) Total infused PN volume: ☐☐☐☐ mL
2) PN amino acid (AA): ☐☐☐ g
3) PN kcal: ☐☐☐☐ kcal
4) Tube feeding protein: ☐☐☐ g
5) Tube feeding kcal: ☐☐☐☐ kcal
6) Oral food protein: ☐☐☐ g
7) Oral food kcal: ☐☐☐☐ kcal
8) IV fluids kcal: ☐☐☐☐ kcal
9) Propofol kcal: ☐☐☐☐ kcal
10) Total protein/amino acid: ☐☐☐ g
11) Total kcal: ☐☐☐☐ kcal
12) Total Insulin administered: ☐☐☐☐ units

B. Blood Glucose

Provide the serial blood glucose and time of the measurement for each of the three time intervals specified. Use the value first recorded within the time interval if there is more than one value available. If there is no value available within the time interval, provide the value closest to the time interval. *(Enter '999' if a blood glucose value is not available.)*

1) 2200 - 2400: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*
2) 0500 - 0700: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*
3) 1400 - 1600: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*

C. SOFA SCORE

Provide the SOFA score for each category, and the SOFA score total. *(Enter zeros if a SOFA Score is not available.)*

1) Respiration: ☐ 3) Liver: ☐ 5) Cen. Nervous System: ☐
2) Coagulation: ☐ 4) Cardiovascular: ☐ 6) Renal: ☐
→ **TOTAL** *(add 1-6)*: ☐☐

D. NOTES ON CLINICAL COURSE

Print legibly any comments pertaining to clinical outcomes, fluid status and/or enteral or parenteral nutrition administration.

VALIDATION: Narrative provided? ☐ No ☐ Yes

DataFax #012 Plate #031 Visit #003

GLND **DAY 7 FOLLOW-UP FORM**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*)

Section 2. Hospital Information

1. Is the patient still hospitalized? ☐ Yes ☐ No → If no, date released from hospital *(skip to Section 4 after completing the date)*: ☐☐ *month* ☐☐ *day* ☐☐ *year*

2. Is the patient still in the SICU? ☐ Yes ☐ No → If no, date released from SICU *(skip to 2.5 after completing the date)*: ☐☐ *month* ☐☐ *day* ☐☐ *year*

3. Is Acute Respiratory Distress Syndrome present (fractional PaO_2/FIO_2 ratio of <200 regardless of positive end-expiratory pressure; presence of bilateral infiltration on frontal chest x-rays; and pulmonary artery wedge pressure at ≤ 18 mmHg when measured, or no clinical evidence of left atrial hypertension)? ☐ Yes ☐ No
If new, date first present: ☐☐ *month* ☐☐ *day* ☐☐ *year*

4. Is the patient on mechanical ventilation? ☐ Yes ☐ No → If removed from ventilation since the last follow-up, date removed: ☐☐ *month* ☐☐ *day* ☐☐ *year*

5. Is the patient receiving the study PN? ☐ Yes ☐ No → If taken off the study PN since the last follow-up, time and date the study PN stopped: ☐☐:☐☐ *(24 hour clock)* ☐☐ *month* ☐☐ *day* ☐☐ *year*

6. Provide the patient's current body weight *(enter '999.9' if not available)*: ☐☐☐.☐ kg
Date patient weighed: ☐☐ *month* ☐☐ *day* ☐☐ *year*

Section 3. New Nosocomial Infections

1. Has the patient exhibited evidence of new nosocomial infection(s) since the last follow-up? ☐ Yes ☐ No

If yes, make sure the infections log is updated, and the appropriate forms are completed and faxed to the data center.

Section 4. Adverse Events

1. Has the patient experienced any adverse events since the last follow-up? ☐ Yes ☐ No
2. If yes to #1, was the adverse event serious? ☐ Yes ☐ No

If the patient has experienced an adverse event, make sure the AE Log Worksheet is current and that the appropriate AE or SAE Case Report Form is completed and faxed to the data center.

Section 5. Concomitant Medications

1. Has the patient had a change in concomitant medications since the last follow-up? ☐ Yes ☐ No
2. If yes to #1, update the Concomitant Medications Form. Updates include new medications, changes in antibiotic dose and the stop of previously indicated medications since baseline. You do not need to repeat previously reported medications if there has not been a change.

☐ Mark this box when the Concomitant Medications Form has been updated and faxed in.

REMINDER: Day 3, 7, 14, 21 and 28 Blood Draws must take place REGARDLESS of when the patient is discharged.

Fax this form to the Data Coordinating Center toll free at 866-477-1298.

DAY 14 PLASMA & SERUM STORAGE FORM

TAB PAGE

DataFax #012 Plate #015 Visit #004

DataFax #012 Plate #016 Visit #004

DAY 14 FOLLOW-UP FORM

TAB PAGE

DataFax #012 Plate #032 Visit #004

GLND **DAY XX FOLLOW-UP FORM**

A day is defined as the 24-hour period beginning at your institution's PN hang time and ending the following day. Please use this definition when filling out the items in this section, as appropriate.

Only complete this form if the patient has been hospitalized for at least some portion of Day XX, XX, XX, XX, XX, XX or XX.

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (F M L) Form Completed By (Initials): ☐☐☐ (F M L)

Section 1: Day XX Date Form Completed: ☐☐ (month) ☐☐ (day) ☐☐ (year)

A. Actual Nutritional Intake

Provide the daily parenteral and enteral nutritional intake. All items should indicate the total per day. *(Enter zeros if the patient did not receive the indicated item.)*

1) Total infused PN volume: ☐☐☐☐ mL
2) PN amino acid (AA): ☐☐☐ g
3) PN kcal: ☐☐☐☐ kcal
4) Tube feeding protein: ☐☐☐ g
5) Tube feeding kcal: ☐☐☐☐ kcal
6) Oral food protein: ☐☐☐ g
7) Oral food kcal: ☐☐☐☐ kcal
8) IV fluids kcal: ☐☐☐☐ kcal
9) Propofol kcal: ☐☐☐☐ kcal
10) Total protein/amino acid: ☐☐☐ g
11) Total kcal: ☐☐☐☐ kcal
12) Total Insulin administered: ☐☐☐☐ units

B. Blood Glucose

Provide the serial blood glucose and time of the measurement for each of the three time intervals specified. Use the value first recorded within the time interval if there is more than one value available. If there is no value available within the time interval, provide the value closest to the time interval. *(Enter '999' if a blood glucose value is not available.)*

1) 2200 - 2400: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*
2) 0500 - 0700: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*
3) 1400 - 1600: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*

C. SOFA SCORE

Provide the SOFA score for each category, and the SOFA score total. *(Enter zeros if a SOFA Score is not available.)*

1) Respiration: ☐ 3) Liver: ☐ 5) Cen. Nervous System: ☐
2) Coagulation: ☐ 4) Cardiovascular: ☐ 6) Renal: ☐
→ **TOTAL** *(add 1-6)*: ☐☐

D. NOTES ON CLINICAL COURSE

Print legibly any comments pertaining to clinical outcomes, fluid status and/or enteral or parenteral nutrition administration.

VALIDATION: Narrative provided? ☐ No ☐ Yes

DataFax #012 Plate #033 Visit #004

GLND **DAY XX FOLLOW-UP FORM**

A day is defined as the 24-hour period beginning at your institution's PN hang time and ending the following day. Please use this definition when filling out the items in this section, as appropriate.

Only complete this page of the form if the patient has been hospitalized for at least some portion of this day. Skip to Section 2 on page 8 of this form if the patient was not hospitalized on this day.

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*)

Section 1: Day XX

A. Actual Nutritional Intake

Provide the daily parenteral and enteral nutritional intake. All items should indicate the total per day. *(Enter zeros if the patient did not receive the indicated item.)*

1) Total infused PN volume: ☐☐☐☐ mL
2) PN amino acid (AA): ☐☐☐ g
3) PN kcal: ☐☐☐☐ kcal
4) Tube feeding protein: ☐☐☐ g
5) Tube feeding kcal: ☐☐☐☐ kcal
6) Oral food protein: ☐☐☐ g
7) Oral food kcal: ☐☐☐☐ kcal
8) IV fluids kcal: ☐☐☐☐ kcal
9) Propofol kcal: ☐☐☐☐ kcal
10) Total protein/amino acid: ☐☐☐ g
11) Total kcal: ☐☐☐☐ kcal
12) Total Insulin administered: ☐☐☐☐ units

B. Blood Glucose

Provide the serial blood glucose and time of the measurement for each of the three time intervals specified. Use the value first recorded within the time interval if there is more than one value available. If there is no value available within the time interval, provide the value closest to the time interval. *(Enter '999' if a blood glucose value is not available.)*

1) 2200 - 2400: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*
2) 0500 - 0700: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*
3) 1400 - 1600: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*

C. SOFA SCORE

Provide the SOFA score for each category, and the SOFA score total. *(Enter zeros if a SOFA Score is not available.)*

1) Respiration: ☐ 3) Liver: ☐ 5) Cen. Nervous System: ☐
2) Coagulation: ☐ 4) Cardiovascular: ☐ 6) Renal: ☐
→ **TOTAL** *(add 1-6)*: ☐☐

D. NOTES ON CLINICAL COURSE

Print legibly any comments pertaining to clinical outcomes, fluid status and/or enteral or parenteral nutrition administration.

VALIDATION: Narrative provided? ☐ No ☐ Yes

DataFax #012 Plate #034 Visit #004

GLND **DAY XX FOLLOW-UP FORM**

A day is defined as the 24-hour period beginning at your institution's PN hang time and ending the following day. Please use this definition when filling out the items in this section, as appropriate.

Only complete this page of the form if the patient has been hospitalized for at least some portion of this day. Skip to Section 2 on page 8 of this form if the patient was not hospitalized on this day.

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*)

Section 1: Day XX

A. Actual Nutritional Intake

Provide the daily parenteral and enteral nutritional intake. All items should indicate the total per day. *(Enter zeros if the patient did not receive the indicated item.)*

1) Total infused PN volume: ☐☐☐☐ mL
2) PN amino acid (AA): ☐☐☐ g
3) PN kcal: ☐☐☐☐ kcal
4) Tube feeding protein: ☐☐☐ g
5) Tube feeding kcal: ☐☐☐☐ kcal
6) Oral food protein: ☐☐☐ g
7) Oral food kcal: ☐☐☐☐ kcal
8) IV fluids kcal: ☐☐☐☐ kcal
9) Propofol kcal: ☐☐☐☐ kcal
10) Total protein/amino acid: ☐☐☐ g
11) Total kcal: ☐☐☐☐ kcal
12) Total Insulin administered: ☐☐☐☐ units

B. Blood Glucose

Provide the serial blood glucose and time of the measurement for each of the three time intervals specified. Use the value first recorded within the time interval if there is more than one value available. If there is no value available within the time interval, provide the value closest to the time interval. *(Enter '999' if a blood glucose value is not available.)*

1) 2200 - 2400: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*
2) 0500 - 0700: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*
3) 1400 - 1600: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*

C. SOFA SCORE

Provide the SOFA score for each category, and the SOFA score total. *(Enter zeros if a SOFA Score is not available.)*

1) Respiration: ☐ 3) Liver: ☐ 5) Cen. Nervous System: ☐
2) Coagulation: ☐ 4) Cardiovascular: ☐ 6) Renal: ☐
→ **TOTAL** *(add 1-6)*: ☐☐

D. NOTES ON CLINICAL COURSE

Print legibly any comments pertaining to clinical outcomes, fluid status and/or enteral or parenteral nutrition administration.

VALIDATION: Narrative provided? ☐ No ☐ Yes

DataFax #012 Plate #035 Visit #004

GLND **DAY XX FOLLOW-UP FORM**

A day is defined as the 24-hour period beginning at your institution's PN hang time and ending the following day. Please use this definition when filling out the items in this section, as appropriate.

Only complete this page of the form if the patient has been hospitalized for at least some portion of this day. Skip to Section 2 on page 8 of this form if the patient was not hospitalized on this day.

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*)

Section 1: Day XX

A. Actual Nutritional Intake

Provide the daily parenteral and enteral nutritional intake. All items should indicate the total per day. *(Enter zeros if the patient did not receive the indicated item.)*

1) Total infused PN volume: ☐☐☐☐ mL
2) PN amino acid (AA): ☐☐☐ g
3) PN kcal: ☐☐☐☐ kcal
4) Tube feeding protein: ☐☐☐ g
5) Tube feeding kcal: ☐☐☐☐ kcal
6) Oral food protein: ☐☐☐ g
7) Oral food kcal: ☐☐☐☐ kcal
8) IV fluids kcal: ☐☐☐☐ kcal
9) Propofol kcal: ☐☐☐☐ kcal
10) Total protein/amino acid: ☐☐☐ g
11) Total kcal: ☐☐☐☐ kcal
12) Total Insulin administered: ☐☐☐☐ units

B. Blood Glucose

Provide the serial blood glucose and time of the measurement for each of the three time intervals specified. Use the value first recorded within the time interval if there is more than one value available. If there is no value available within the time interval, provide the value closest to the time interval. *(Enter '999' if a blood glucose value is not available.)*

1) 2200 - 2400: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*
2) 0500 - 0700: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*
3) 1400 - 1600: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*

C. SOFA SCORE

Provide the SOFA score for each category, and the SOFA score total. *(Enter zeros if a SOFA Score is not available.)*

1) Respiration: ☐ 3) Liver: ☐ 5) Cen. Nervous System: ☐
2) Coagulation: ☐ 4) Cardiovascular: ☐ 6) Renal: ☐

→ **TOTAL** *(add 1-6)*: ☐☐

D. NOTES ON CLINICAL COURSE

Print legibly any comments pertaining to clinical outcomes, fluid status and/or enteral or parenteral nutrition administration.

VALIDATION: Narrative provided? ☐ No ☐ Yes

DataFax #012 Plate #036 Visit #004

GLND **DAY XX FOLLOW-UP FORM**

A day is defined as the 24-hour period beginning at your institution's PN hang time and ending the following day. Please use this definition when filling out the items in this section, as appropriate.

Only complete this page of the form if the patient has been hospitalized for at least some portion of this day. Skip to Section 2 on page 8 of this form if the patient was not hospitalized on this day.

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*)

Section 1: Day XX

A. Actual Nutritional Intake

Provide the daily parenteral and enteral nutritional intake. All items should indicate the total per day. *(Enter zeros if the patient did not receive the indicated item.)*

1) Total infused PN volume: ☐☐☐☐ mL
2) PN amino acid (AA): ☐☐☐ g
3) PN kcal: ☐☐☐☐ kcal
4) Tube feeding protein: ☐☐☐ g
5) Tube feeding kcal: ☐☐☐☐ kcal
6) Oral food protein: ☐☐☐ g
7) Oral food kcal: ☐☐☐☐ kcal
8) IV fluids kcal: ☐☐☐☐ kcal
9) Propofol kcal: ☐☐☐☐ kcal
10) Total protein/amino acid: ☐☐☐ g
11) Total kcal: ☐☐☐☐ kcal
12) Total Insulin administered: ☐☐☐☐ units

B. Blood Glucose

Provide the serial blood glucose and time of the measurement for each of the three time intervals specified. Use the value first recorded within the time interval if there is more than one value available. If there is no value available within the time interval, provide the value closest to the time interval. *(Enter '999' if a blood glucose value is not available.)*

1) 2200 - 2400: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*
2) 0500 - 0700: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*
3) 1400 - 1600: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*

C. SOFA SCORE

Provide the SOFA score for each category, and the SOFA score total. *(Enter zeros if a SOFA Score is not available.)*

1) Respiration: ☐ 3) Liver: ☐ 5) Cen. Nervous System: ☐
2) Coagulation: ☐ 4) Cardiovascular: ☐ 6) Renal: ☐
→ **TOTAL** *(add 1-6)*: ☐☐

D. NOTES ON CLINICAL COURSE

Print legibly any comments pertaining to clinical outcomes, fluid status and/or enteral or parenteral nutrition administration.

VALIDATION: Narrative provided? ☐ No ☐ Yes

DataFax #012 Plate #037 Visit #004

GLND **DAY XX FOLLOW-UP FORM**

A day is defined as the 24-hour period beginning at your institution's PN hang time and ending the following day. Please use this definition when filling out the items in this section, as appropriate.

Only complete this page of the form if the patient has been hospitalized for at least some portion of this day. Skip to Section 2 on page 8 of this form if the patient was not hospitalized on this day.

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*)

Section 1: Day XX

A. Actual Nutritional Intake

Provide the daily parenteral and enteral nutritional intake. All items should indicate the total per day. *(Enter zeros if the patient did not receive the indicated item.)*

1) Total infused PN volume: ☐☐☐☐ mL
2) PN amino acid (AA): ☐☐☐ g
3) PN kcal: ☐☐☐☐ kcal
4) Tube feeding protein: ☐☐☐ g
5) Tube feeding kcal: ☐☐☐☐ kcal
6) Oral food protein: ☐☐☐ g
7) Oral food kcal: ☐☐☐☐ kcal
8) IV fluids kcal: ☐☐☐☐ kcal
9) Propofol kcal: ☐☐☐☐ kcal
10) Total protein/amino acid: ☐☐☐ g
11) Total kcal: ☐☐☐☐ kcal
12) Total Insulin administered: ☐☐☐☐ units

B. Blood Glucose

Provide the serial blood glucose and time of the measurement for each of the three time intervals specified. Use the value first recorded within the time interval if there is more than one value available. If there is no value available within the time interval, provide the value closest to the time interval. *(Enter '999' if a blood glucose value is not available.)*

1) 2200 - 2400: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*
2) 0500 - 0700: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*
3) 1400 - 1600: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*

C. SOFA SCORE

Provide the SOFA score for each category, and the SOFA score total. *(Enter zeros if a SOFA Score is not available.)*

1) Respiration: ☐ 3) Liver: ☐ 5) Cen. Nervous System: ☐
2) Coagulation: ☐ 4) Cardiovascular: ☐ 6) Renal: ☐
→ **TOTAL** *(add 1-6)*: ☐☐

D. NOTES ON CLINICAL COURSE

Print legibly any comments pertaining to clinical outcomes, fluid status and/or enteral or parenteral nutrition administration.

VALIDATION: Narrative provided? ☐ No ☐ Yes

DataFax #012 Plate #038 Visit #004

GLND **DAY XX FOLLOW-UP FORM**

A day is defined as the 24-hour period beginning at your institution's PN hang time and ending the following day. Please use this definition when filling out the items in this section, as appropriate.

Only complete this page of the form if the patient has been hospitalized for at least some portion of this day. Skip to Section 2 on page 8 of this form if the patient was not hospitalized on this day.

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*)

Section 1: Day XX

A. Actual Nutritional Intake

Provide the daily parenteral and enteral nutritional intake. All items should indicate the total per day. *(Enter zeros if the patient did not receive the indicated item.)*

1) Total infused PN volume: ☐☐☐☐ mL
2) PN amino acid (AA): ☐☐☐ g
3) PN kcal: ☐☐☐☐ kcal
4) Tube feeding protein: ☐☐☐ g
5) Tube feeding kcal: ☐☐☐☐ kcal
6) Oral food protein: ☐☐☐ g
7) Oral food kcal: ☐☐☐☐ kcal
8) IV fluids kcal: ☐☐☐☐ kcal
9) Propofol kcal: ☐☐☐☐ kcal
10) Total protein/amino acid: ☐☐☐ g
11) Total kcal: ☐☐☐☐ kcal
12) Total Insulin administered: ☐☐☐☐ units

B. Blood Glucose

Provide the serial blood glucose and time of the measurement for each of the three time intervals specified. Use the value first recorded within the time interval if there is more than one value available. If there is no value available within the time interval, provide the value closest to the time interval. *(Enter '999' if a blood glucose value is not available.)*

1) 2200 - 2400: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*
2) 0500 - 0700: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*
3) 1400 - 1600: ☐☐☐ mg/dL → Time of measurement: ☐☐:☐☐ *(24 hour clock)*

C. SOFA SCORE

Provide the SOFA score for each category, and the SOFA score total. *(Enter zeros if a SOFA Score is not available.)*

1) Respiration: ☐ 3) Liver: ☐ 5) Cen. Nervous System: ☐
2) Coagulation: ☐ 4) Cardiovascular: ☐ 6) Renal: ☐
→ **TOTAL** *(add 1-6)*: ☐☐

D. NOTES ON CLINICAL COURSE

Print legibly any comments pertaining to clinical outcomes, fluid status and/or enteral or parenteral nutrition administration.

VALIDATION: Narrative provided? ☐ No ☐ Yes

DataFax #012 Plate #039 Visit #004

GLND **DAY 14 FOLLOW-UP FORM**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (F M L)

Section 2. Hospital Information

1. Is the patient still hospitalized? ☐ Yes ☐ No → If no, date released from hospital *(skip to Section 4 after completing the date)*: ☐☐ month ☐☐ day ☐☐ year

2. Is the patient still in the SICU? ☐ Yes ☐ No → If no, date released from SICU *(skip to 2.5 after completing the date)*: ☐☐ month ☐☐ day ☐☐ year

3. Is Acute Respiratory Distress Syndrome present (fractional PaO_2/FIO_2 ratio of <200 regardless of positive end-expiratory pressure; presence of bilateral infiltration on frontal chest x-rays; and pulmonary artery wedge pressure at ≤ 18 mmHg when measured, or no clinical evidence of left atrial hypertension)? ☐ Yes ☐ No
If new, date first present: ☐☐ month ☐☐ day ☐☐ year

4. Is the patient on mechanical ventilation? ☐ Yes ☐ No → If removed from ventilation since the last follow-up, date removed: ☐☐ month ☐☐ day ☐☐ year

5. Is the patient receiving the study PN? ☐ Yes ☐ No → If taken off the study PN since the last follow-up, time and date the study PN stopped: ☐☐:☐☐ *(24 hour clock)* ☐☐ month ☐☐ day ☐☐ year

6. Provide the patient's current body weight *(enter '999.9' if not available)*: ☐☐☐.☐ kg
Date patient weighed: ☐☐ month ☐☐ day ☐☐ year

Section 3. New Nosocomial Infections

1. Has the patient exhibited evidence of new nosocomial infection(s) since the last follow-up? ☐ Yes ☐ No

If yes, make sure the infections log is updated, and the appropriate forms are completed and faxed to the data center.

Section 4. Adverse Events

1. Has the patient experienced any adverse events since the last follow-up? ☐ Yes ☐ No
2. If yes to #1, was the adverse event serious? ☐ Yes ☐ No

If the patient has experienced an adverse event, make sure the AE Log Worksheet is current and that the appropriate AE or SAE Case Report Form is completed and faxed to the data center.

Section 5. Concomitant Medications

1. Has the patient had a change in concomitant medications since the last follow-up? ☐ Yes ☐ No
2. If yes to #1, update the Concomitant Medications Form. Updates include new medications, changes in antibiotic dose and the stop of previously indicated medications since baseline. You do not need to repeat previously reported medications if there has not been a change.

☐ Mark this box when the Concomitant Medications Form has been updated and faxed in.

REMINDER: Day 3, 7, 14, 21 and 28 Blood Draws must take place REGARDLESS of when the patient is discharged.

Fax this form to the Data Coordinating Center toll free at 866-477-1298.

DAY 21 PLASMA & SERUM STORAGE FORM

TAB PAGE

DataFax #012 Plate #015 Visit #005

DataFax #012 Plate #016 Visit #005

DAY 21 FOLLOW-UP FORM

TAB PAGE

DataFax #012 Plate #032 Visit #005

DataFax #012 Plate #033 Visit #005

DataFax #012 Plate #034 Visit #005

DataFax #012 Plate #035 Visit #005

DataFax #012 Plate #036 Visit #005

DataFax #012 Plate #037 Visit #005

DataFax #012 Plate #038 Visit #005

DataFax #012 Plate #039 Visit #005

DAY 28 PLASMA & SERUM STORAGE FORM

TAB PAGE

DataFax #012 Plate #015 Visit #006

DataFax #012 Plate #016 Visit #006

DAY 28 FOLLOW-UP FORM

TAB PAGE

DataFax #012 Plate #032 Visit #006

DataFax #012 Plate #033 Visit #006

DataFax #012 Plate #034 Visit #006

DataFax #012 Plate #035 Visit #006

DataFax #012 Plate #036 Visit #006

DataFax #012 Plate #037 Visit #006

DataFax #012 Plate #038 Visit #006

DataFax #012 Plate #039 Visit #006

DAY 35 FOLLOW-UP FORM

TAB PAGE

DataFax #012 Plate #040 Visit #007

GLND **DAY XX FOLLOW-UP FORM** **Page 1 of 2**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (F M L) Form Completed By (Initials): ☐☐☐ (F M L)

Date Form Completed: ☐☐ (month) ☐☐ (day) ☐☐ (year)

NOTE: If the patient remains hospitalized past Day XX, complete a Day XX Follow-up form. Do not complete this form if the patient was not hospitalized past Day XX.

Section 1. Hospital Information

1. Is the patient still hospitalized? ☐ Yes ☐ No → If no, date released from hospital *(skip to Section 3 after completing the date)*: ☐☐ (month) ☐☐ (day) ☐☐ (year)

2. Is the patient still in the SICU? ☐ Yes ☐ No → If no, date released from SICU *(skip to 1.5 after completing the date)*: ☐☐ (month) ☐☐ (day) ☐☐ (year)

3. Is Acute Respiratory Distress Syndrome present (fractional PaO_2/FIO_2 ratio of <200 regardless of positive end-expiratory pressure; presence of bilateral infiltration on frontal chest x-rays; and pulmonary artery wedge pressure at ≤ 18 mmHg when measured, or no clinical evidence of left atrial hypertension)? ☐ Yes ☐ No
If new, date first present: ☐☐ (month) ☐☐ (day) ☐☐ (year)

4. Is the patient on mechanical ventilation? ☐ Yes ☐ No → If removed from ventilation since the last follow-up, date removed: ☐☐ (month) ☐☐ (day) ☐☐ (year)

5. Is the patient receiving the study PN? ☐ Yes ☐ No → If taken off the study PN since the last follow-up, time and date the study PN stopped: ☐☐:☐☐ *(24 hour clock)* ☐☐ (month) ☐☐ (day) ☐☐ (year)

Note: As indicated in the Manual of Operations, patients are not to receive the study PN for more than 28 days. If the patient requires PN beyond 28 days, the study PN and GLN dipeptide must be discontinued. Once the study PN has been discontinued, answer 'No' and indicate the study PN stop time and date above (if the study PN is stopped Day XX-XX).

6. Provide the patient's current body weight *(enter '999.9' if not available)*: ☐☐☐.☐ kg
Date patient weighed: ☐☐ (month) ☐☐ (day) ☐☐ (year)

Section 2. New Nosocomial Infections

1. Has the patient exhibited evidence of new nosocomial infection(s) since the last follow-up? ☐ Yes ☐ No

If yes, make sure the infections log is updated, and the appropriate forms are completed and faxed to the data center.

DataFax #012 Plate #041 Visit #007

GLND **DAY XX FOLLOW-UP FORM** **Page 2 of 2**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*)

Section 3. Adverse Events

1. Has the patient experienced any adverse events since the last follow-up? ☐ Yes ☐ No
2. If yes to #1, was the adverse event serious? ☐ Yes ☐ No

If the patient has experienced an adverse event, make sure the AE Log Worksheet is current and that the appropriate AE or SAE Case Report Form is completed and faxed to the data center.

Section 4. Concomitant Medications

1. Has the patient had a change in concomitant medications since the last follow-up? ☐ Yes ☐ No
2. If yes to #1, update the Concomitant Medications Form. Updates include new medications, changes in antibiotic dose and the stop of previously indicated medications since the last follow-up. You do not need to repeat previously reported medications if there has not been a change.

☐ Mark this box when the Concomitant Medications Form has been updated and faxed in.

Section 5. Narrative

Print legibly any comments pertaining to clinical outcomes, fluid status and/or enteral or parenteral nutrition administration.

VALIDATION: Narrative provided? ☐ No ☐ Yes

Fax this form to the Data Coordinating Center toll free at 866-477-1298.

DAY 42 FOLLOW-UP FORM

TAB PAGE

DataFax #012 Plate #040 Visit #008

DataFax #012 Plate #041 Visit #008

ADDITIONAL FOLLOW-UP FORMS

TAB PAGE

If the patient remains hospitalized past Day 42, the DCC will provide you with additional follow-up forms, as needed. Please place those forms in this section.

30 DAYS POST-STUDY DRUG DISCONTINUATION FORM

TAB PAGE

DataFax #012 Plate #042 Visit #012

GLND **30 DAYS POST-STUDY DRUG DISCONTINUATION FORM** **Page 1 of 1**

Note: Do not complete this form if the patient has been CONTINUOUSLY hospitalized since study enrollment.

Contact the patient and/or their family, or the primary care physician's office to obtain the following information.

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*) Form Completed By (Initials): ☐☐☐ (*F M L*)

Date Form Completed: ☐☐ (*month*) ☐☐ (*day*) ☐☐ (*year*) Date Study Drug Discontinued: ☐☐ (*month*) ☐☐ (*day*) ☐☐ (*year*)

Section 1. Information Source

1. Contact for this follow-up:
   - ☐ Patient and/or family
   - ☐ Primary care physician's office
   - ☐ Other *(specify):* _____

Section 2. Re-Hospitalization

1. Has the patient died since the last follow up visit? ☐ No ☐ Yes *(If yes, skip to Section 3 and make sure to complete the Death and Serious Adverse Event Forms.)*

2. Has the patient been re-hospitalized? ☐ No *(If no, skip to Section 3.)* ☐ Yes → If yes, date re-admitted to hospital: ☐☐ (*month*) ☐☐ (*day*) ☐☐ (*year*)

   Note: Re-hospitalization within 30 days of being released from the hospital is considered a serious adverse event. If the patient has been re-hospitalized within 30 days of being released, make sure the AE Log is current and that the SAE Case Report Form is completed and faxed to the data center.

3. Is the patient in the SICU? ☐ No ☐ Yes → If yes, date admitted to SICU: ☐☐ (*month*) ☐☐ (*day*) ☐☐ (*year*)

Section 3. Adverse Events

1. Has the patient experienced any adverse events since the last follow-up? ☐ Yes ☐ No
2. If yes to #1, was the adverse event serious? ☐ Yes ☐ No

If the patient has experienced an adverse event, make sure the AE Log Worksheet is current and that the appropriate AE or SAE Case Report Form is completed and faxed to the data center.

Section 4. Narrative

Print legibly any comments pertaining to clinical outcomes, fluid status and/or enteral or parenteral nutrition administration.

VALIDATION: Narrative provided? ☐ No ☐ Yes

2 MONTH POST-ENROLLMENT FOLLOW-UP TELEPHONE CALL

TAB PAGE

DataFax #012 Plate #043 Visit #013

GLND X MONTH POST-ENROLLMENT FOLLOW-UP TELEPHONE CALL

Contact the patient and/or their family, or the primary care physician's office XXX days post-enrollment (± 7 days) to obtain the following information. Attempt to contact an information source even if it is outside the 14-day window.

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*) Form Completed By (Initials): ☐☐☐ (*F M L*)

Date Patient Enrolled: ☐☐ (*month*) ☐☐ (*day*) ☐☐ (*year*) Date of Phone Call: ☐☐ (*month*) ☐☐ (*day*) ☐☐ (*year*)

Section 1. Information Source

1. Contact for this follow-up:
   - ☐ Patient and/or family
   - ☐ Primary care physician's office
   - ☐ Other *(specify):* _____

Section 2. Re-Hospitalization

1. Has the patient died since the last follow up visit? ☐ No ☐ Yes *(If yes, skip to Section 3 and make sure to complete the Death Form.)*

2. Has the patient been re-hospitalized? ☐ No *(If no, skip to Section 3.)* ☐ Yes → If yes, date re-admitted to hospital: ☐☐ (*month*) ☐☐ (*day*) ☐☐ (*year*)

3. Is the patient in the SICU? ☐ No ☐ Yes → If yes, date admitted to SICU: ☐☐ (*month*) ☐☐ (*day*) ☐☐ (*year*)

Section 3. Narrative

Print legibly any comments pertaining to re-hospitalization, death and/or anything else that might be relevant.

VALIDATION: Narrative provided? ☐ No ☐ Yes

Fax this form to the Data Coordinating Center toll free at 866-477-1298.

4 MONTH POST-ENROLLMENT FOLLOW-UP TELEPHONE CALL

TAB PAGE

DataFax #012 Plate #043 Visit #014

6 MONTH POST-ENROLLMENT FOLLOW-UP TELEPHONE CALL

TAB PAGE

DataFax #012 Plate #043 Visit #015

PI SIGN-OFF FORM: PATIENT CLOSE-OUT

TAB PAGE

DataFax #012 Plate #044 Visit #016

GLND **PI SIGN-OFF FORM: PATIENT CLOSE-OUT** **Page 1 of 1**

The site Principal Investigator should review all the CRFs and complete and sign this form when the patient is closed-out or leaves the study.

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*) Form Completed By (Initials): ☐☐☐ (*F M L*)

Date Form Completed: ☐☐ ☐☐ ☐☐ (*month day year*)

I have reviewed all case report forms and related documents pertaining to this patient and have verified that they accurately reflect source documentation for this patient.

Investigator Name *(please print)*

☐ *VALIDATION:* Mark box if signature provided.

Investigator Signature

Fax this form to the Data Coordinating Center toll free at 866-477-1298.

UNSCHEDULED FORMS

This part of the binder contains forms that will be completed on an "as needed" basis.

SUSPECTED NOSOCOMIAL INFECTIONS

TAB PAGE

DataFax #012 Plate #101 Visit #101

GLND **SUSPECTED NOSOCOMIAL INFECTION #XX**

Complete a Suspected Nosocomial Infection Form for each suspected infection.

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*) Form Completed By (Initials): ☐☐☐ (*F M L*)

Infection Number from Nosocomial Infections Log: ☐☐ Date Form Completed: ☐☐ (*month*) ☐☐ (*day*) ☐☐ (*year*)

Section 1. Suspected Infection Information

1. Date of suspected infection onset: ☐☐ (*month*) ☐☐ (*day*) ☐☐ (*year*) Maximum body temperature on date of suspected infection: ☐☐.☐ °C

Section 2. Cultured Organisms

1. Was a culture related to this infection obtained? ☐ No *(skip to Section 3)* ☐ Yes
2. Was a culture related to this infection positive? ☐ No *(skip to Section 3)* ☐ Yes
3. Positive cultures: For each positive culture indicate the cultured organism and site using the following codes.

Cultured Organism Codes:

01 = Methicillin-susceptible Staphylococcus aureus (MSSA)
02 = Methicillin-resistant Staphylococcus aureus (MRSA)
03 = Coagulase-negative Staphylococcus species
04 = Vancomycin-susceptible Enterococcus faecalis
05 = Vancomycin-resistant Enterococcus faecalis
06 = Vancomycin-susceptible Enterococcus faecium
07 = Vancomycin-resistant Enterococcus faecium
08 = Klebsiella pneumoniae
09 = Other Klebsiella species
10 = Pseudomonas aeruginosa
11 = Streptococcus pneumoniae
12 = Escherichia coli
13 = Acinetobacter baumannii
14 = Enterobacter cloace
15 = Enterobacter aerogenes
16 = Clostridium difficile
17 = Candida albicans
18 = Candida glabrata
19 = Candida tropicalis
20 = Other fungal species
21 = Other

Culture Site Codes:

1 = Blood
2 = Urine
3 = Wound
4 = Sputum / Tracheal Aspirate
5 = BAL
6 = CSF
7 = Stool
8 = Catheter Tip
9 = Other

NOTE: For each positive culture obtained, obtain a copy of the Culture and Sensitivity Report. Black out any personal identifiers, and affix/complete a Culture Report Label (provided in your Coordinator Binder) to each page of the report. Mark the box in the appropriate culture item below and indicate the date the report is faxed. *If there is a delay in obtaining any of the reports, complete and fax this form without the report. When the culture report is obtained, mark the appropriate box below, indicate the date, and re-fax the page you modify with the report.*

	Cultured Organism Code	Extended spectrum beta lactamase producer?	Culture Site Code	Within 24 Hours: No. Sets Collected	Within 24 Hours: No. Sets Positive
A. Positive Culture 1:	☐☐ →	If 08 or 09: ☐ No ☐ Yes	☐ →	If Site=1: ☐	☐

If 09, 20 or 21, specify organism (both genus and species): _____

Received by lab - Time: ☐☐:☐☐ (*24 hour clock*) Date: ☐☐ (*month*) ☐☐ (*day*) ☐☐ (*year*)

☐ Mark this box and indicate date when Culture and Sensitivity Report is faxed: ☐☐ (*month*) ☐☐ (*day*) ☐☐ (*year*)

Additional positive cultures continued next page.

DataFax #012 Plate #102 Visit #101

GLND **SUSPECTED NOSOCOMIAL INFECTION #XX**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (F M L)

Section 2. Cultured Organisms (continued)

3. Positive cultures: For each positive culture indicate the cultured organism and site using the codes on page 1.

	Cultured Organism Code	Extended spectrum beta lactamase producer?	Culture Site Code	Within 24 Hours: No. Sets Collected	Within 24 Hours: No. Sets Positive
B. Positive Culture 2:	☐☐	If 08 or 09: ☐ No ☐ Yes	☐	If Site=1: ☐	☐
C. Positive Culture 3:	☐☐	If 08 or 09: ☐ No ☐ Yes	☐	If Site=1: ☐	☐
D. Positive Culture 4:	☐☐	If 08 or 09: ☐ No ☐ Yes	☐	If Site=1: ☐	☐
E. Positive Culture 5:	☐☐	If 08 or 09: ☐ No ☐ Yes	☐	If Site=1: ☐	☐

If 09, 20 or 21, specify organism (both genus and species): _____

Received by lab - Time: ☐☐:☐☐ *(24 hour clock)* Date: ☐☐ ☐☐ ☐☐ *month day year*

☐ Mark this box and indicate date when Culture and Sensitivity Report is faxed: ☐☐ ☐☐ ☐☐ *month day year*

DataFax #012 Plate #103 Visit #101

GLND **SUSPECTED NOSOCOMIAL INFECTION #XX**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ *F M L*

Section 3. Infection Site and Type

1. Was the suspected infection confirmed as a nosocomial infection using the Site and Type descriptions contained in Appendix 7 of the study Manual of Operations? *(mark 'X' just one of the following):*

☐ Yes, this is definitely a nosocomial infection, both site and type codes determined *(indicate both site and type codes in the boxes at right).*

☐ Yes, this is definitely a nosocomial infection, site code determined but type uncertain *(indicate site code in the boxes at right, write "UNK" in the last three boxes of type code).*

SITE CODE **TYPE CODE**
☐☐☐☐ - ☐☐☐☐

☐ No, this is definitely not a nosocomial infection *(Put a '0' in all site/type code boxes and skip to Section 5)*.

☐ Undetermined, it is not clear whether or not this is a nosocomial infection. *(Put a '9' in all site/type code boxes. Complete the remainder of this form. Fax it with all medical record progress notes and laboratory, radiographic and microbial culture reports relevant to the possible infection to the DCC toll free at 1-866-477-1298.)*

Section 4. New Infection at Previous Infection Site

1. Is this a new infection at the same site as a previous infection in the patient? ☐ No *(skip to Section 5)* ☐ Yes

2. New infection criteria:

A. Has there been at least a two week interval between infections? ☐ No ☐ Yes

B. Is there evidence of resolution of the initial infection (e.g., defervescence after antimicrobial agents started, interval improvement in other clinical signs/symptoms)? ☐ No ☐ Yes

C. Is there a combination of new signs and symptoms and/or radiographic evidence or other diagnostic testing as outlined in the CDC guidelines? ☐ No ☐ Yes

D. Is there completion of the initial antibiotic course? ☐ No ☐ Yes

E. If this infection is a bloodstream infection (BSI) with the same organism, have there been interval negative blood cultures? ☐ N/A ☐ No ☐ Yes

DataFax #012 Plate #104 Visit #101

GLND **SUSPECTED NOSOCOMIAL INFECTION #XX**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*)

Section 5. Narrative

Provide a legible narrative with any comments concerning this suspected infection, including treatment and resolution as appropriate.

VALIDATION: Narrative provided? ☐ No ☐ Yes

☐ *VALIDATION:* Mark box if signature provided.

Investigator Name *(please print)* Investigator Signature

Fax this form to the Data Coordinating Center toll free at 866-477-1298.

DataFax #012 Plate #101 Visit #102

DataFax #012 Plate #102 Visit #102

DataFax #012 Plate #103 Visit #102

DataFax #012 Plate #104 Visit #102

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ADVERSE EVENTS

TAB PAGE

DataFax #012 Plate #201 Visit #201

GLND **ADVERSE EVENT FORM - AE #XX**

Complete an Adverse Event Form for each non-serious adverse event on the patient's Adverse Event Log.
If the adverse event is serious, do not complete this form, instead complete a Serious Adverse Event Form.

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*) Form Completed By (Initials): ☐☐☐ (*F M L*)

Date Form Completed: ☐☐ (*month*) ☐☐ (*day*) ☐☐ (*year*)

Section 1. Adverse Event Type

1. Adverse Event Number from Adverse Events Log: ☐☐
2. Adverse Event Code from Adverse Events Log: ☐☐
3. Type of adverse event *(mark 'X' one of the following)*:

- ☐ A. Respiratory distress / failure requiring new intubation or re-intubation and mechanical ventilation
- ☐ B. Tracheostomy
- ☐ C. Clinically significant pulmonary aspiration (requiring change in respiratory care)
- ☐ D. Pneumothorax
- ☐ E. Pulmonary emboli
- ☐ F. Wound dehiscence
- ☐ G. New onset of clinically significant hemorrhage at any body site (requiring blood transfusion)
- ☐ H. Mechanical intestinal obstruction
- ☐ I. Development of worsening renal function (serum creatinine $\geq$ 5.0 mg/dL or requiring dialysis therapy)
- ☐ J. Development of worsening hepatic function (total serum billirubin $\geq$ 15.0 mg/dL)
- ☐ K. Myocardial infarction
- ☐ L. Cerebrovascular accident
- ☐ M. Re-admission required to the ICU / SICU setting
- ☐ N. New onset significant skin rash requiring systemic or topical treatment
- ☐ O. Hyperglycemia > 250 mg/dL
- ☐ P. Non-infectious pancreatitis
- ☐ Q. Encephalopathy

Section 2. Adverse Event Information

1. Date of adverse event onset *(mm/dd/yy)*: ☐☐ ☐☐ ☐☐
2. Does your site's IRB require that this adverse event be reported to them?
   NOTE: Most IRB's require that serious or unexpected adverse events are reported within 1-10 days.
   ☐ No ☐ Yes *(if Yes, indicate date reported to your IRB; mm/dd/yy):* ☐☐ ☐☐ ☐☐
3. Is the adverse event related to treatment in the study?
   ☐ Definitely related ☐ Possibly related ☐ Unsure ☐ Probably not related ☐ Definitely not related
4. Has the adverse event been resolved?
   ☐ Yes *(if Yes, specify date resolved in box at right and explain resolution including any treatment given in Section 3 below)* →
   ☐ No → A. If no, skip the date field at right, detail the adverse event in Section 3 on the next page, and fax this form to the Data Center. You will be reminded in your site's Quality Control Reports that this AE has not been resolved.
   B. If and when this AE is subsequently resolved, mark the box at right and indicate the date resolved in the box above. Amend the narrative in Section 3 indicating any treatment and the resolution of the AE. Re-fax this page of the form.

Date this AE is Resolved:
☐☐ (*month*) ☐☐ (*day*) ☐☐ (*year*)
(use '00' for unknown month or day)

☐ Mark if/when AE is subsequently resolved.

DataFax #012 Plate #202 Visit #201

GLND **ADVERSE EVENT FORM - AE #XX**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*)

Section 3. Narrative

Provide a legible narrative with any comments concerning this adverse event, including treatment and resolution as appropriate.

VALIDATION: Narrative provided? ☐ No ☐ Yes

☐ *VALIDATION:* Mark box if signature provided.

Investigator Name *(please print)* Investigator Signature

Fax this form to the Data Coordinating Center toll free at 866-477-1298.

DataFax #012 Plate #201 Visit #202

DataFax #012 Plate #202 Visit #202

DataFax #012 Plate #201 Visit #203

DataFax #012 Plate #202 Visit #203

DataFax #012 Plate #201 Visit #204

DataFax #012 Plate #202 Visit #204

DataFax #012 Plate #201 Visit #205

DataFax #012 Plate #202 Visit #205

DataFax #012 Plate #201 Visit #206

DataFax #012 Plate #202 Visit #206

DataFax #012 Plate #201 Visit #207

DataFax #012 Plate #202 Visit #207

DataFax #012 Plate #201 Visit #208

DataFax #012 Plate #202 Visit #208

DataFax #012 Plate #201 Visit #209

DataFax #012 Plate #202 Visit #209

DataFax #012 Plate #201 Visit #210

DataFax #012 Plate #202 Visit #210

DataFax #012 Plate #201 Visit #211

DataFax #012 Plate #202 Visit #211

DataFax #012 Plate #201 Visit #212

DataFax #012 Plate #202 Visit #212

DataFax #012 Plate #201 Visit #213

DataFax #012 Plate #202 Visit #213

DataFax #012 Plate #201 Visit #214

DataFax #012 Plate #202 Visit #214

DataFax #012 Plate #201 Visit #215

DataFax #012 Plate #202 Visit #215

DataFax #012 Plate #201 Visit #216

DataFax #012 Plate #202 Visit #216

DataFax #012 Plate #201 Visit #217

DataFax #012 Plate #202 Visit #217

DataFax #012 Plate #201 Visit #218

DataFax #012 Plate #202 Visit #218

DataFax #012 Plate #201 Visit #219

DataFax #012 Plate #202 Visit #219

DataFax #012 Plate #201 Visit #220

DataFax #012 Plate #202 Visit #220

SERIOUS ADVERSE EVENTS

TAB PAGE

DataFax #012 Plate #203 Visit #301

GLND **SERIOUS ADVERSE EVENT FORM - SAE #XX** **Page 1 of 2**

Complete a Serious Adverse Event Form for each serious adverse event on the patient's Adverse Event Log.
NOTE: ALL SAE'S ARE SUBJECT TO EXPEDITED REPORTING. COMPLETE AND FAX THIS FORM IMMEDIATELY.
If the adverse event is not serious, do not complete this form; instead complete an Adverse Event Form.

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (F M L) Form Completed By (Initials): ☐☐☐ (F M L)

Date Form Completed: ☐☐ (month) ☐☐ (day) ☐☐ (year)

Section 1. Adverse Event Type

1. Adverse Event Number from Adverse Events Log: ☐☐
2. Adverse Event Code from Adverse Events Log: ☐☐
3. Type of adverse event *(mark 'X' one of the following)*:
   - ☐ A. Death *(complete Death Form)*
   - ☐ B. Anaphylactic reaction associated with study drug administration
     If 'B', mark 'X' all that apply:
     - ☐ a. New onset severe bronchospasm
     - ☐ b. Facial edema
     - ☐ c. Stridor and/or hypotension defined as MAP < 60 *(MAP = 1/3 [systolic BP - diastolic BP] + diastolic BP)*
   - ☐ C. Seizure
   - ☐ D. Cardiopulmonary arrest
   - ☐ E. Re-hospitalization within 30 days of study drug discontinuation
   - ☐ F. Re-operation within 30 days of study drug discontinuation
   - ☐ G. New cancer diagnosis
   - ☐ H. Congenital anomaly / disorder

Section 2. Serious Adverse Event Information

1. Date of serious adverse event onset *(mm/dd/yy)*: ☐☐ ☐☐ ☐☐
2. Does your site's IRB require that this serious adverse event be reported to them?
   NOTE: Most IRB's require that serious or unexpected adverse events are reported within 1-10 days.
   ☐ No ☐ Yes *(if Yes, indicate date reported to your IRB; mm/dd/yy):* ☐☐ ☐☐ ☐☐
3. Is the serious adverse event related to treatment in the study?
   ☐ Definitely related ☐ Possibly related ☐ Unsure ☐ Probably not related ☐ Definitely not related
4. Has the serious adverse event been resolved?
   ☐ Yes *(if Yes, specify date resolved in box at right and explain resolution including any treatment given in Section 3 below)* →
   ☐ No →
   A. If no, skip the date field at right, detail the serious adverse event in Section 3 on the next page, and fax this form to the Data Center. You will be reminded in your site's Quality Control Reports that this SAE has not been resolved.
   B. If and when this SAE is subsequently resolved, mark the box at right and indicate the date resolved in the box above. Amend the narrative in Section 3 indicating any treatment and the resolution of the SAE. Re-fax this page of the form.

Date this SAE is Resolved:
☐☐ (month) ☐☐ (day) ☐☐ (year)
(use '00' for unknown month or day)

☐ Mark if/when SAE is subsequently resolved.

DataFax #012 Plate #204 Visit #301

GLND **SERIOUS ADVERSE EVENT FORM - SAE #XX** **Page 2 of 2**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*)

Section 3. Narrative

Provide a legible narrative with any comments concerning this serious adverse event, including treatment and resolution as appropriate.

VALIDATION: Narrative provided? ☐ No ☐ Yes

☐ *VALIDATION:* Mark box if signature provided.

Investigator Name *(please print)* Investigator Signature

Fax this form to the Data Coordinating Center toll free at 866-477-1298.

DataFax #012 Plate #203 Visit #302

DataFax #012 Plate #204 Visit #302

DataFax #012 Plate #203 Visit #303

DataFax #012 Plate #204 Visit #303

DataFax #012 Plate #203 Visit #304

DataFax #012 Plate #204 Visit #304

DataFax #012 Plate #203 Visit #305

DataFax #012 Plate #204 Visit #305

DataFax #012 Plate #203 Visit #306

DataFax #012 Plate #204 Visit #306

DataFax #012 Plate #203 Visit #307

DataFax #012 Plate #204 Visit #307

DataFax #012 Plate #203 Visit #308

DataFax #012 Plate #204 Visit #308

DataFax #012 Plate #203 Visit #309

DataFax #012 Plate #204 Visit #309

DataFax #012 Plate #203 Visit #310

DataFax #012 Plate #204 Visit #310

DEATH FORM

TAB PAGE

DataFax #012 Plate #205 Visit #351

GLND **DEATH FORM**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (F M L) Form Completed By (Initials): ☐☐☐ (F M L)

Section 1. Patient Mortality Data

Date Form Completed: ☐☐ (month) ☐☐ (day) ☐☐ (year)

1. Date of patient's death: ☐☐ (month) ☐☐ (day) ☐☐ (year)

2. Date of the event (if applicable) that was the cause of death: ☐☐ (month) ☐☐ (day) ☐☐ (year)

3. Has the cause of death been determined? ☐ No *(if No, skip to 1.4)* ☐ Yes *(if Yes, mark 'X' all of the following that apply):*

- ☐ 1. Acute Respiratory Distress Syndrome (ARDS)
- ☐ 2. Sepsis (overwhelming infection)
- ☐ 3. Ischemic or Hemorrhagic stroke
- ☐ 4. Myocardial Infarction
- ☐ 5. Pulmonary Embolus
- ☐ 6. Complications of acute ischemia of internal organ
- ☐ 7. Ruptured blood vessel
- ☐ 8. Wound dehiscence
- ☐ 9. Systemic hemorrhage
- ☐ 10. Congestive or other type of heart failure
- ☐ 11. Multiple organ failure
- ☐ 12. Uncontrolled seizure
- ☐ 13. Other *(specify)*: _____

4. Was an autopsy performed? ☐ No ☐ Yes ☐ Unknown

If yes, obtain a copy of the autopsy report and fax it to the DCC (be sure to black out any personal identifiers, and write both the GLND Patient ID number and initials on each page faxed). Mark the box below and indicate the date the report is faxed. If there is a delay in obtaining the report, complete and fax this form without the report. When the autopsy report is obtained, mark the box below, indicate the date, and re-fax this page with the report.

☐ Mark this box and indicate the date when the autopsy report is faxed: ☐☐ (month) ☐☐ (day) ☐☐ (year)

Section 2. Supplemental Documents

1. Supplemental documents submitted pertaining to the patients death *(mark 'X' all that apply):*

For each supplemental document page submitted to the DCC pertinent to the patient's death, mark the box below and indicate the date submitted. Black out any personal identifiers on each page. Complete and affix a Supplemental Document Label from your coordinator's binder to each page.

NOTE: If there is a delay in obtaining any of the supplemental documents, do not delay faxing this form. Fax it upon completion with whatever supplemental documents you have obtained, marking only those boxes for the documents being submitted with the form. When you obtain additional document(s), alter this page by marking the box for the additional document(s), indicate the new date submitted, and re-fax this page with the additional documents.

- ☐ A. Death certificate data — Date of submission: ☐☐ (month) ☐☐ (day) ☐☐ (year)
- ☐ B. Progress notes — Date of submission: ☐☐ (month) ☐☐ (day) ☐☐ (year)
- ☐ C. Hospital discharge summaries from the time of hospitalization nearest to or at time of death — Date of submission: ☐☐ (month) ☐☐ (day) ☐☐ (year)
- ☐ D. Coroner's investigation reports — Date of submission: ☐☐ (month) ☐☐ (day) ☐☐ (year)
- ☐ E. Other relevant pathology reports — Date of submission: ☐☐ (month) ☐☐ (day) ☐☐ (year)

DataFax #012 Plate #206 Visit #351

GLND **DEATH FORM**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*)

Section 3. Narrative

If not completed on another complication specific form, please print or type a brief narrative summary of the events leading to the patient's death.

VALIDATION: Narrative provided? ☐ No ☐ Yes

☐ *VALIDATION:* Mark box if signature provided.

Investigator Name *(please print)* Investigator Signature

Fax this form to the Data Coordinating Center toll free at 866-477-1298.

LOST TO FOLLOW-UP FORM

TAB PAGE

DataFax #012 Plate #051 Visit #051

GLND **LOST TO FOLLOW-UP FORM**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*) Form Completed By (Initials): ☐☐☐ (*F M L*)

Date form completed: ☐☐ (*month*) ☐☐ (*day*) ☐☐ (*year*)

Section 1. Lost to Follow-Up

1. Has the patient been declared lost to follow-up? ☐ No ☐ Yes

2. If yes, last date of contact: ☐☐ (*month*) ☐☐ (*day*) ☐☐ (*year*)

Section 2. Patient Withdrew Consent

1. Did the patient withdraw consent? ☐ No ☐ Yes

2. If yes, effective date of withdrawal: ☐☐ (*month*) ☐☐ (*day*) ☐☐ (*year*)

Section 3. Contact Re-established

If contact is re-established with the patient, complete this section.

1. Has contact been re-established with the patient? ☐ No ☐ Yes

2. If yes, date contact re-established: ☐☐ (*month*) ☐☐ (*day*) ☐☐ (*year*)

Section 4. Narrative

Print legibly any comments pertaining to this form.

VALIDATION: Narrative provided? ☐ No ☐ Yes

☐ *VALIDATION:* Mark box if signature provided.

Investigator Name *(please print)* Investigator Signature

Fax this form to the Data Coordinating Center toll free at 866-477-1298.

WORKSHEETS AND LOGS

This part of the binder contains all the worksheets and logs.

PN ORDER CALCULATION WORKSHEETS

TAB PAGE

NUTRITIONAL INTAKE LOG

TAB PAGE

GLND **DAILY PARENTERAL AND ENTERAL NUTRITIONAL INTAKE LOG SOURCE DOCUMENT** **Page 1 of 4**

GLND ID No.: [ ] - [ ][ ][ ][ ] Participant Initials: [ ][ ][ ] (*F M L*) Form Completed By (Initials): [ ][ ][ ] (*F M L*)

Note: A day is defined as the 24-hour period beginning at your institution's PN hang time and ending the following day. Please use this definition when filling out the items in the nutritional intake log, as appropriate.

Week 1 Daily Parenteral and Enteral Nutritional Intake

Provide the daily parenteral and enteral nutritional intake. All items should indicate the total per day.

	Total infused PN volume (mL)	PN amino acid (AA) (g)	PN kcal (kcal)	Tube feeding protein (g)	Tube feeding kcal (kcal)	Oral food protein (g)	Oral food kcal (kcal)	IV fluids kcal (kcal)	Propofol kcal (kcal)	Total protein/ amino acid (g)	Total kcal (kcal)	Total Insulin administered (units)
Day 1: __/__/__												
Day 2: __/__/__												
Day 3: __/__/__												
Day 4: __/__/__												
Day 5: __/__/__												
Day 6: __/__/__												
Day 7: __/__/__												

GLND **DAILY PARENTERAL AND ENTERAL NUTRITIONAL INTAKE LOG SOURCE DOCUMENT** **Page 2 of 4**

GLND ID No.: [ ] - [ ][ ][ ][ ] Participant Initials: [ ][ ][ ] (*F M L*) Form Completed By (Initials): [ ][ ][ ] (*F M L*)

Note: A day is defined as the 24-hour period beginning at your institution's PN hang time and ending the following day. Please use this definition when filling out the items in the nutritional intake log, as appropriate.

Week 2 Daily Parenteral and Enteral Nutritional Intake

Provide the daily parenteral and enteral nutritional intake. All items should indicate the total per day.

	Total infused PN volume (mL)	PN amino acid (AA) (g)	PN kcal (kcal)	Tube feeding protein (g)	Tube feeding kcal (kcal)	Oral food protein (g)	Oral food kcal (kcal)	IV fluids kcal (kcal)	Propofol kcal (kcal)	Total protein/ amino acid (g)	Total kcal (kcal)	Total Insulin administered (units)
Day 8: __/__/__												
Day 9: __/__/__												
Day 10: __/__/__												
Day 11: __/__/__												
Day 12: __/__/__												
Day 13: __/__/__												
Day 14: __/__/__												

GLND **DAILY PARENTERAL AND ENTERAL NUTRITIONAL INTAKE LOG SOURCE DOCUMENT** **Page 3 of 4**

GLND ID No.: [ ] - [ ][ ][ ][ ] Participant Initials: [ ][ ][ ] (*F M L*) Form Completed By (Initials): [ ][ ][ ] (*F M L*)

Note: A day is defined as the 24-hour period beginning at your institution's PN hang time and ending the following day. Please use this definition when filling out the items in the nutritional intake log, as appropriate.

Week 3 Daily Parenteral and Enteral Nutritional Intake

Provide the daily parenteral and enteral nutritional intake. All items should indicate the total per day.

	Total infused PN volume (mL)	PN amino acid (AA) (g)	PN kcal (kcal)	Tube feeding protein (g)	Tube feeding kcal (kcal)	Oral food protein (g)	Oral food kcal (kcal)	IV fluids kcal (kcal)	Propofol kcal (kcal)	Total protein/ amino acid (g)	Total kcal (kcal)	Total Insulin administered (units)
Day 15: __/__/__												
Day 16: __/__/__												
Day 17: __/__/__												
Day 18: __/__/__												
Day 19: __/__/__												
Day 20: __/__/__												
Day 21: __/__/__												

GLND **DAILY PARENTERAL AND ENTERAL NUTRITIONAL INTAKE LOG SOURCE DOCUMENT** **Page 4 of 4**

GLND ID No.: [ ] - [ ][ ][ ][ ] Participant Initials: [ ][ ][ ] (*F M L*) Form Completed By (Initials): [ ][ ][ ] (*F M L*)

Note: A day is defined as the 24-hour period beginning at your institution's PN hang time and ending the following day. Please use this definition when filling out the items in the nutritional intake log, as appropriate.

Week 4 Daily Parenteral and Enteral Nutritional Intake

Provide the daily parenteral and enteral nutritional intake. All items should indicate the total per day.

	Total infused PN volume (mL)	PN amino acid (AA) (g)	PN kcal (kcal)	Tube feeding protein (g)	Tube feeding kcal (kcal)	Oral food protein (g)	Oral food kcal (kcal)	IV fluids kcal (kcal)	Propofol kcal (kcal)	Total protein/ amino acid (g)	Total kcal (kcal)	Total Insulin administered (units)
Day 22: __/__/__												
Day 23: __/__/__												
Day 24: __/__/__												
Day 25: __/__/__												
Day 26: __/__/__												
Day 27: __/__/__												
Day 28: __/__/__												

SOFA SCORING WORKSHEET

TAB PAGE

GLND **SOFA SCORING WORKSHEET SOURCE DOCUMENT**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*) Form Completed By (Initials): ☐☐☐ (*F M L*) Date Form Completed: ☐☐ (*month*) ☐☐ (*day*) ☐☐ (*year*)

Day 1 SOFA Score Worksheet

Mark ('X') the appropriate box for each category (1-6) row and record the corresponding SOFA point value, from the top column, in the box at the end of each row. Use the last lab value, blood gas, or assessment if there is no value for the current day, and use the last SOFA score for this organ.

SOFA Points →	**0**	**1**	**2**	**3**	**4**	**Point Value**
1. *Respiration* PaO_2/FiO_2 mm Hg	☐ ≥ 400 or (extubated & no ABG[A])	☐ < 400	☐ < 300	☐ < 200 with respiratory support	☐ < 100 with respiratory support	☐
2. *Coagulation* Platelets x $10^3/mm^3$	☐ ≥ 150	☐ < 150	☐ < 100	☐ < 50	☐ < 20	☐
3. *Liver* Bilirubin, mg/dL	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 5.9	☐ 6.0 - 11.9	☐ ≥ 12.0 *or* MARS[B]	☐
4. *Cardiovascular* Hypotension	☐ MAP[C] ≥ 70 mm Hg, No hypotension	☐ MAP[C] < 70 mm Hg	☐ Dopamine ≤ 5* *or* Dobutamine (any dose)	☐ Dopamine > 5* *or* Epinephrine ≤ 0.1* *or* Norepinephrine ≤ 0.1* *or* Vasopressin	☐ Dopamine > 15* *or* Epinephrine > 0.1* *or* Norepinephrine > 0.1* *or* CAD[D]	☐
5. *Central Nervous System* Glasgow coma score (GCS)	☐ 15	☐ 13 - 14	☐ 10 - 12	☐ 6 - 9 *or* ICP	☐ < 6	☐
6. *Renal* Creatinine, mg/dL or urine output	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 3.4	☐ 3.5 - 4.9 *or* < 500 mL/day	☐ ≥ 5.0 *or* < 200 mL/day *or* dialysis	☐

* units = µg/kg/min

A. ABG: Arterial Blood Gas

B. MARS: Molecular Absorbent Recirculating System

C. MAP: Mean Arterial Pressure = 1/3 (Systolic Pressure - Diastolic Pressure) + Diastolic Pressure

D. CAD: Cardiac Assist Devices

GLND **SOFA SCORING WORKSHEET SOURCE DOCUMENT**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (F M L) Form Completed By (Initials): ☐☐☐ (F M L) Date Form Completed: ☐☐ (month) ☐☐ (day) ☐☐ (year)

Day 2 SOFA Score Worksheet

Mark ('X') the appropriate box for each category (1-6) row and record the corresponding SOFA point value, from the top column, in the box at the end of each row. Use the last lab value, blood gas, or assessment if there is no value for the current day, and use the last SOFA score for this organ.

SOFA Points →	**0**	**1**	**2**	**3**	**4**	**Point Value**
1. *Respiration* PaO_2/FiO_2 mm Hg	☐ ≥ 400 or (extubated & no ABG[A])	☐ < 400	☐ < 300	☐ < 200 with respiratory support	☐ < 100 with respiratory support	☐
2. *Coagulation* Platelets x $10^3/mm^3$	☐ ≥ 150	☐ < 150	☐ < 100	☐ < 50	☐ < 20	☐
3. *Liver* Bilirubin, mg/dL	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 5.9	☐ 6.0 - 11.9	☐ ≥ 12.0 *or* MARS[B]	☐
4. *Cardiovascular* Hypotension	☐ MAP[C] ≥ 70 mm Hg, No hypotension	☐ MAP[C] < 70 mm Hg	☐ Dopamine ≤ 5* *or* Dobutamine (any dose)	☐ Dopamine > 5* *or* Epinephrine ≤ 0.1* *or* Norepinephrine ≤ 0.1* *or* Vasopressin	☐ Dopamine > 15* *or* Epinephrine > 0.1* *or* Norepinephrine > 0.1* *or* CAD[D]	☐
5. *Central Nervous System* Glasgow coma score (GCS)	☐ 15	☐ 13 - 14	☐ 10 - 12	☐ 6 - 9 *or* ICP	☐ < 6	☐
6. *Renal* Creatinine, mg/dL or urine output	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 3.4	☐ 3.5 - 4.9 *or* < 500 mL/day	☐ ≥ 5.0 *or* < 200 mL/day *or* dialysis	☐

* units = µg/kg/min

A. ABG: Arterial Blood Gas

B. MARS: Molecular Absorbent Recirculating System

C. MAP: Mean Arterial Pressure = 1/3 (Systolic Pressure - Diastolic Pressure) + Diastolic Pressure

D. CAD: Cardiac Assist Devices

GLND **SOFA SCORING WORKSHEET SOURCE DOCUMENT**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (F M L) Form Completed By (Initials): ☐☐☐ (F M L) Date Form Completed: ☐☐ (month) ☐☐ (day) ☐☐ (year)

Day 3 SOFA Score Worksheet

Mark ('X') the appropriate box for each category (1-6) row and record the corresponding SOFA point value, from the top column, in the box at the end of each row. Use the last lab value, blood gas, or assessment if there is no value for the current day, and use the last SOFA score for this organ.

SOFA Points →	**0**	**1**	**2**	**3**	**4**	**Point Value**
1. *Respiration* PaO_2/FiO_2 mm Hg	☐ ≥ 400 or (extubated & no ABG[A])	☐ < 400	☐ < 300	☐ < 200 with respiratory support	☐ < 100 with respiratory support	☐
2. *Coagulation* Platelets x $10^3/mm^3$	☐ ≥ 150	☐ < 150	☐ < 100	☐ < 50	☐ < 20	☐
3. *Liver* Bilirubin, mg/dL	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 5.9	☐ 6.0 - 11.9	☐ ≥ 12.0 *or* MARS[B]	☐
4. *Cardiovascular* Hypotension	☐ MAP[C] ≥ 70 mm Hg, No hypotension	☐ MAP[C] < 70 mm Hg	☐ Dopamine ≤ 5* *or* Dobutamine (any dose)	☐ Dopamine > 5* *or* Epinephrine ≤ 0.1* *or* Norepinephrine ≤ 0.1* *or* Vasopressin	☐ Dopamine > 15* *or* Epinephrine > 0.1* *or* Norepinephrine > 0.1* *or* CAD[D]	☐
5. *Central Nervous System* Glasgow coma score (GCS)	☐ 15	☐ 13 - 14	☐ 10 - 12	☐ 6 - 9 *or* ICP	☐ < 6	☐
6. *Renal* Creatinine, mg/dL or urine output	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 3.4	☐ 3.5 - 4.9 *or* < 500 mL/day	☐ ≥ 5.0 *or* < 200 mL/day *or* dialysis	☐

* units = µg/kg/min

A. ABG: Arterial Blood Gas

B. MARS: Molecular Absorbent Recirculating System

C. MAP: Mean Arterial Pressure = 1/3 (Systolic Pressure - Diastolic Pressure) + Diastolic Pressure

D. CAD: Cardiac Assist Devices

GLND **SOFA SCORING WORKSHEET SOURCE DOCUMENT**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (F M L) Form Completed By (Initials): ☐☐☐ (F M L) Date Form Completed: ☐☐ (month) ☐☐ (day) ☐☐ (year)

Day 4 SOFA Score Worksheet

Mark ('X') the appropriate box for each category (1-6) row and record the corresponding SOFA point value, from the top column, in the box at the end of each row. Use the last lab value, blood gas, or assessment if there is no value for the current day, and use the last SOFA score for this organ.

SOFA Points →	**0**	**1**	**2**	**3**	**4**	**Point Value**
1. *Respiration* PaO_2/FiO_2 mm Hg	☐ ≥ 400 or (extubated & no ABG[A])	☐ < 400	☐ < 300	☐ < 200 with respiratory support	☐ < 100 with respiratory support	☐
2. *Coagulation* Platelets x $10^3/mm^3$	☐ ≥ 150	☐ < 150	☐ < 100	☐ < 50	☐ < 20	☐
3. *Liver* Bilirubin, mg/dL	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 5.9	☐ 6.0 - 11.9	☐ ≥ 12.0 *or* MARS[B]	☐
4. *Cardiovascular* Hypotension	☐ MAP[C] ≥ 70 mm Hg, No hypotension	☐ MAP[C] < 70 mm Hg	☐ Dopamine ≤ 5* *or* Dobutamine (any dose)	☐ Dopamine > 5* *or* Epinephrine ≤ 0.1* *or* Norepinephrine ≤ 0.1* *or* Vasopressin	☐ Dopamine > 15* *or* Epinephrine > 0.1* *or* Norepinephrine > 0.1* *or* CAD[D]	☐
5. *Central Nervous System* Glasgow coma score (GCS)	☐ 15	☐ 13 - 14	☐ 10 - 12	☐ 6 - 9 *or* ICP	☐ < 6	☐
6. *Renal* Creatinine, mg/dL or urine output	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 3.4	☐ 3.5 - 4.9 *or* < 500 mL/day	☐ ≥ 5.0 *or* < 200 mL/day *or* dialysis	☐

* units = µg/kg/min

A. ABG: Arterial Blood Gas

B. MARS: Molecular Absorbent Recirculating System

C. MAP: Mean Arterial Pressure = 1/3 (Systolic Pressure - Diastolic Pressure) + Diastolic Pressure

D. CAD: Cardiac Assist Devices

GLND **SOFA SCORING WORKSHEET SOURCE DOCUMENT**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (F M L) Form Completed By (Initials): ☐☐☐ (F M L) Date Form Completed: ☐☐ (month) ☐☐ (day) ☐☐ (year)

Day 5 SOFA Score Worksheet

Mark ('X') the appropriate box for each category (1-6) row and record the corresponding SOFA point value, from the top column, in the box at the end of each row. Use the last lab value, blood gas, or assessment if there is no value for the current day, and use the last SOFA score for this organ.

SOFA Points →	**0**	**1**	**2**	**3**	**4**	**Point Value**
1. *Respiration* PaO_2/FiO_2 mm Hg	☐ ≥ 400 or (extubated & no ABG[A])	☐ < 400	☐ < 300	☐ < 200 with respiratory support	☐ < 100 with respiratory support	☐
2. *Coagulation* Platelets x $10^3/mm^3$	☐ ≥ 150	☐ < 150	☐ < 100	☐ < 50	☐ < 20	☐
3. *Liver* Bilirubin, mg/dL	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 5.9	☐ 6.0 - 11.9	☐ ≥ 12.0 *or* MARS[B]	☐
4. *Cardiovascular* Hypotension	☐ MAP[C] ≥ 70 mm Hg, No hypotension	☐ MAP[C] < 70 mm Hg	☐ Dopamine ≤ 5* *or* Dobutamine (any dose)	☐ Dopamine > 5* *or* Epinephrine ≤ 0.1* *or* Norepinephrine ≤ 0.1* *or* Vasopressin	☐ Dopamine > 15* *or* Epinephrine > 0.1* *or* Norepinephrine > 0.1* *or* CAD[D]	☐
5. *Central Nervous System* Glasgow coma score (GCS)	☐ 15	☐ 13 - 14	☐ 10 - 12	☐ 6 - 9 *or* ICP	☐ < 6	☐
6. *Renal* Creatinine, mg/dL or urine output	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 3.4	☐ 3.5 - 4.9 *or* < 500 mL/day	☐ ≥ 5.0 *or* < 200 mL/day *or* dialysis	☐

* units = µg/kg/min

A. ABG: Arterial Blood Gas

B. MARS: Molecular Absorbent Recirculating System

C. MAP: Mean Arterial Pressure = 1/3 (Systolic Pressure - Diastolic Pressure) + Diastolic Pressure

D. CAD: Cardiac Assist Devices

GLND **SOFA SCORING WORKSHEET SOURCE DOCUMENT**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (F M L) Form Completed By (Initials): ☐☐☐ (F M L) Date Form Completed: ☐☐ (month) ☐☐ (day) ☐☐ (year)

Day 6 SOFA Score Worksheet

Mark ('X') the appropriate box for each category (1-6) row and record the corresponding SOFA point value, from the top column, in the box at the end of each row. Use the last lab value, blood gas, or assessment if there is no value for the current day, and use the last SOFA score for this organ.

SOFA Points →	**0**	**1**	**2**	**3**	**4**	**Point Value**
1. *Respiration* PaO_2/FiO_2 mm Hg	☐ ≥ 400 or (extubated & no ABG[A])	☐ < 400	☐ < 300	☐ < 200 with respiratory support	☐ < 100 with respiratory support	☐
2. *Coagulation* Platelets x $10^3/mm^3$	☐ ≥ 150	☐ < 150	☐ < 100	☐ < 50	☐ < 20	☐
3. *Liver* Bilirubin, mg/dL	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 5.9	☐ 6.0 - 11.9	☐ ≥ 12.0 *or* MARS[B]	☐
4. *Cardiovascular* Hypotension	☐ MAP[C] ≥ 70 mm Hg, No hypotension	☐ MAP[C] < 70 mm Hg	☐ Dopamine ≤ 5* *or* Dobutamine (any dose)	☐ Dopamine > 5* *or* Epinephrine ≤ 0.1* *or* Norepinephrine ≤ 0.1* *or* Vasopressin	☐ Dopamine > 15* *or* Epinephrine > 0.1* *or* Norepinephrine > 0.1* *or* CAD[D]	☐
5. *Central Nervous System* Glasgow coma score (GCS)	☐ 15	☐ 13 - 14	☐ 10 - 12	☐ 6 - 9 *or* ICP	☐ < 6	☐
6. *Renal* Creatinine, mg/dL or urine output	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 3.4	☐ 3.5 - 4.9 *or* < 500 mL/day	☐ ≥ 5.0 *or* < 200 mL/day *or* dialysis	☐

* units = µg/kg/min

A. ABG: Arterial Blood Gas

B. MARS: Molecular Absorbent Recirculating System

C. MAP: Mean Arterial Pressure = 1/3 (Systolic Pressure - Diastolic Pressure) + Diastolic Pressure

D. CAD: Cardiac Assist Devices

GLND **SOFA SCORING WORKSHEET SOURCE DOCUMENT**

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Day 7 SOFA Score Worksheet

Mark ('X') the appropriate box for each category (1-6) row and record the corresponding SOFA point value, from the top column, in the box at the end of each row. Use the last lab value, blood gas, or assessment if there is no value for the current day, and use the last SOFA score for this organ.

SOFA Points →	**0**	**1**	**2**	**3**	**4**	**Point Value**
1. *Respiration* PaO_2/FiO_2 mm Hg	☐ ≥ 400 or (extubated & no ABG[A])	☐ < 400	☐ < 300	☐ < 200 with respiratory support	☐ < 100 with respiratory support	☐
2. *Coagulation* Platelets x $10^3/mm^3$	☐ ≥ 150	☐ < 150	☐ < 100	☐ < 50	☐ < 20	☐
3. *Liver* Bilirubin, mg/dL	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 5.9	☐ 6.0 - 11.9	☐ ≥ 12.0 *or* MARS[B]	☐
4. *Cardiovascular* Hypotension	☐ MAP[C] ≥ 70 mm Hg, No hypotension	☐ MAP[C] < 70 mm Hg	☐ Dopamine ≤ 5* *or* Dobutamine (any dose)	☐ Dopamine > 5* *or* Epinephrine ≤ 0.1* *or* Norepinephrine ≤ 0.1* *or* Vasopressin	☐ Dopamine > 15* *or* Epinephrine > 0.1* *or* Norepinephrine > 0.1* *or* CAD[D]	☐
5. *Central Nervous System* Glasgow coma score (GCS)	☐ 15	☐ 13 - 14	☐ 10 - 12	☐ 6 - 9 *or* ICP	☐ < 6	☐
6. *Renal* Creatinine, mg/dL or urine output	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 3.4	☐ 3.5 - 4.9 *or* < 500 mL/day	☐ ≥ 5.0 *or* < 200 mL/day *or* dialysis	☐

* units = µg/kg/min

A. ABG: Arterial Blood Gas

B. MARS: Molecular Absorbent Recirculating System

C. MAP: Mean Arterial Pressure = 1/3 (Systolic Pressure - Diastolic Pressure) + Diastolic Pressure

D. CAD: Cardiac Assist Devices

GLND **SOFA SCORING WORKSHEET SOURCE DOCUMENT**

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Day 8 SOFA Score Worksheet

Mark ('X') the appropriate box for each category (1-6) row and record the corresponding SOFA point value, from the top column, in the box at the end of each row. Use the last lab value, blood gas, or assessment if there is no value for the current day, and use the last SOFA score for this organ.

SOFA Points →	**0**	**1**	**2**	**3**	**4**	**Point Value**
1. *Respiration* PaO_2/FiO_2 mm Hg	☐ ≥ 400 or (extubated & no ABG[A])	☐ < 400	☐ < 300	☐ < 200 with respiratory support	☐ < 100 with respiratory support	☐
2. *Coagulation* Platelets x $10^3/mm^3$	☐ ≥ 150	☐ < 150	☐ < 100	☐ < 50	☐ < 20	☐
3. *Liver* Bilirubin, mg/dL	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 5.9	☐ 6.0 - 11.9	☐ ≥ 12.0 *or* MARS[B]	☐
4. *Cardiovascular* Hypotension	☐ MAP[C] ≥ 70 mm Hg, No hypotension	☐ MAP[C] < 70 mm Hg	☐ Dopamine ≤ 5* *or* Dobutamine (any dose)	☐ Dopamine > 5* *or* Epinephrine ≤ 0.1* *or* Norepinephrine ≤ 0.1* *or* Vasopressin	☐ Dopamine > 15* *or* Epinephrine > 0.1* *or* Norepinephrine > 0.1* *or* CAD[D]	☐
5. *Central Nervous System* Glasgow coma score (GCS)	☐ 15	☐ 13 - 14	☐ 10 - 12	☐ 6 - 9 *or* ICP	☐ < 6	☐
6. *Renal* Creatinine, mg/dL or urine output	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 3.4	☐ 3.5 - 4.9 *or* < 500 mL/day	☐ ≥ 5.0 *or* < 200 mL/day *or* dialysis	☐

* units = µg/kg/min

A. ABG: Arterial Blood Gas

B. MARS: Molecular Absorbent Recirculating System

C. MAP: Mean Arterial Pressure = 1/3 (Systolic Pressure - Diastolic Pressure) + Diastolic Pressure

D. CAD: Cardiac Assist Devices

GLND **SOFA SCORING WORKSHEET SOURCE DOCUMENT**

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Day 9 SOFA Score Worksheet

Mark ('X') the appropriate box for each category (1-6) row and record the corresponding SOFA point value, from the top column, in the box at the end of each row. Use the last lab value, blood gas, or assessment if there is no value for the current day, and use the last SOFA score for this organ.

SOFA Points →	**0**	**1**	**2**	**3**	**4**	**Point Value**
1. *Respiration* PaO_2/FiO_2 mm Hg	☐ ≥ 400 or (extubated & no ABG[A])	☐ < 400	☐ < 300	☐ < 200 with respiratory support	☐ < 100 with respiratory support	☐
2. *Coagulation* Platelets x $10^3/mm^3$	☐ ≥ 150	☐ < 150	☐ < 100	☐ < 50	☐ < 20	☐
3. *Liver* Bilirubin, mg/dL	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 5.9	☐ 6.0 - 11.9	☐ ≥ 12.0 *or* MARS[B]	☐
4. *Cardiovascular* Hypotension	☐ MAP[C] ≥ 70 mm Hg, No hypotension	☐ MAP[C] < 70 mm Hg	☐ Dopamine ≤ 5* *or* Dobutamine (any dose)	☐ Dopamine > 5* *or* Epinephrine ≤ 0.1* *or* Norepinephrine ≤ 0.1* *or* Vasopressin	☐ Dopamine > 15* *or* Epinephrine > 0.1* *or* Norepinephrine > 0.1* *or* CAD[D]	☐
5. *Central Nervous System* Glasgow coma score (GCS)	☐ 15	☐ 13 - 14	☐ 10 - 12	☐ 6 - 9 *or* ICP	☐ < 6	☐
6. *Renal* Creatinine, mg/dL or urine output	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 3.4	☐ 3.5 - 4.9 *or* < 500 mL/day	☐ ≥ 5.0 *or* < 200 mL/day *or* dialysis	☐

* units = µg/kg/min

A. ABG: Arterial Blood Gas

B. MARS: Molecular Absorbent Recirculating System

C. MAP: Mean Arterial Pressure = 1/3 (Systolic Pressure - Diastolic Pressure) + Diastolic Pressure

D. CAD: Cardiac Assist Devices

GLND **SOFA SCORING WORKSHEET SOURCE DOCUMENT**

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Day 10 SOFA Score Worksheet

Mark ('X') the appropriate box for each category (1-6) row and record the corresponding SOFA point value, from the top column, in the box at the end of each row. Use the last lab value, blood gas, or assessment if there is no value for the current day, and use the last SOFA score for this organ.

SOFA Points →	**0**	**1**	**2**	**3**	**4**	**Point Value**
1. *Respiration* PaO_2/FiO_2 mm Hg	☐ ≥ 400 or (extubated & no ABG[A])	☐ < 400	☐ < 300	☐ < 200 with respiratory support	☐ < 100 with respiratory support	☐
2. *Coagulation* Platelets x $10^3/mm^3$	☐ ≥ 150	☐ < 150	☐ < 100	☐ < 50	☐ < 20	☐
3. *Liver* Bilirubin, mg/dL	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 5.9	☐ 6.0 - 11.9	☐ ≥ 12.0 *or* MARS[B]	☐
4. *Cardiovascular* Hypotension	☐ MAP[C] ≥ 70 mm Hg, No hypotension	☐ MAP[C] < 70 mm Hg	☐ Dopamine ≤ 5* *or* Dobutamine (any dose)	☐ Dopamine > 5* *or* Epinephrine ≤ 0.1* *or* Norepinephrine ≤ 0.1* *or* Vasopressin	☐ Dopamine > 15* *or* Epinephrine > 0.1* *or* Norepinephrine > 0.1* *or* CAD[D]	☐
5. *Central Nervous System* Glasgow coma score (GCS)	☐ 15	☐ 13 - 14	☐ 10 - 12	☐ 6 - 9 *or* ICP	☐ < 6	☐
6. *Renal* Creatinine, mg/dL or urine output	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 3.4	☐ 3.5 - 4.9 *or* < 500 mL/day	☐ ≥ 5.0 *or* < 200 mL/day *or* dialysis	☐

* units = µg/kg/min

A. ABG: Arterial Blood Gas

B. MARS: Molecular Absorbent Recirculating System

C. MAP: Mean Arterial Pressure = 1/3 (Systolic Pressure - Diastolic Pressure) + Diastolic Pressure

D. CAD: Cardiac Assist Devices

GLND **SOFA SCORING WORKSHEET SOURCE DOCUMENT**

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Day 11 SOFA Score Worksheet

Mark ('X') the appropriate box for each category (1-6) row and record the corresponding SOFA point value, from the top column, in the box at the end of each row. Use the last lab value, blood gas, or assessment if there is no value for the current day, and use the last SOFA score for this organ.

SOFA Points →	**0**	**1**	**2**	**3**	**4**	**Point Value**
1. *Respiration* PaO_2/FiO_2 mm Hg	☐ ≥ 400 or (extubated & no ABG[A])	☐ < 400	☐ < 300	☐ < 200 with respiratory support	☐ < 100 with respiratory support	☐
2. *Coagulation* Platelets x $10^3/mm^3$	☐ ≥ 150	☐ < 150	☐ < 100	☐ < 50	☐ < 20	☐
3. *Liver* Bilirubin, mg/dL	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 5.9	☐ 6.0 - 11.9	☐ ≥ 12.0 *or* MARS[B]	☐
4. *Cardiovascular* Hypotension	☐ MAP[C] ≥ 70 mm Hg, No hypotension	☐ MAP[C] < 70 mm Hg	☐ Dopamine ≤ 5* *or* Dobutamine (any dose)	☐ Dopamine > 5* *or* Epinephrine ≤ 0.1* *or* Norepinephrine ≤ 0.1* *or* Vasopressin	☐ Dopamine > 15* *or* Epinephrine > 0.1* *or* Norepinephrine > 0.1* *or* CAD[D]	☐
5. *Central Nervous System* Glasgow coma score (GCS)	☐ 15	☐ 13 - 14	☐ 10 - 12	☐ 6 - 9 *or* ICP	☐ < 6	☐
6. *Renal* Creatinine, mg/dL or urine output	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 3.4	☐ 3.5 - 4.9 *or* < 500 mL/day	☐ ≥ 5.0 *or* < 200 mL/day *or* dialysis	☐

* units = µg/kg/min

A. ABG: Arterial Blood Gas

B. MARS: Molecular Absorbent Recirculating System

C. MAP: Mean Arterial Pressure = 1/3 (Systolic Pressure - Diastolic Pressure) + Diastolic Pressure

D. CAD: Cardiac Assist Devices

GLND **SOFA SCORING WORKSHEET SOURCE DOCUMENT**

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Day 12 SOFA Score Worksheet

Mark ('X') the appropriate box for each category (1-6) row and record the corresponding SOFA point value, from the top column, in the box at the end of each row. Use the last lab value, blood gas, or assessment if there is no value for the current day, and use the last SOFA score for this organ.

SOFA Points →	**0**	**1**	**2**	**3**	**4**	**Point Value**
1. *Respiration* PaO_2/FiO_2 mm Hg	☐ ≥ 400 or (extubated & no ABG[A])	☐ < 400	☐ < 300	☐ < 200 with respiratory support	☐ < 100 with respiratory support	☐
2. *Coagulation* Platelets x $10^3/mm^3$	☐ ≥ 150	☐ < 150	☐ < 100	☐ < 50	☐ < 20	☐
3. *Liver* Bilirubin, mg/dL	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 5.9	☐ 6.0 - 11.9	☐ ≥ 12.0 *or* MARS[B]	☐
4. *Cardiovascular* Hypotension	☐ MAP[C] ≥ 70 mm Hg, No hypotension	☐ MAP[C] < 70 mm Hg	☐ Dopamine ≤ 5* *or* Dobutamine (any dose)	☐ Dopamine > 5* *or* Epinephrine ≤ 0.1* *or* Norepinephrine ≤ 0.1* *or* Vasopressin	☐ Dopamine > 15* *or* Epinephrine > 0.1* *or* Norepinephrine > 0.1* *or* CAD[D]	☐
5. *Central Nervous System* Glasgow coma score (GCS)	☐ 15	☐ 13 - 14	☐ 10 - 12	☐ 6 - 9 *or* ICP	☐ < 6	☐
6. *Renal* Creatinine, mg/dL or urine output	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 3.4	☐ 3.5 - 4.9 *or* < 500 mL/day	☐ ≥ 5.0 *or* < 200 mL/day *or* dialysis	☐

* units = µg/kg/min

A. ABG: Arterial Blood Gas

B. MARS: Molecular Absorbent Recirculating System

C. MAP: Mean Arterial Pressure = 1/3 (Systolic Pressure - Diastolic Pressure) + Diastolic Pressure

D. CAD: Cardiac Assist Devices

GLND **SOFA SCORING WORKSHEET SOURCE DOCUMENT**

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Day 13 SOFA Score Worksheet

Mark ('X') the appropriate box for each category (1-6) row and record the corresponding SOFA point value, from the top column, in the box at the end of each row. Use the last lab value, blood gas, or assessment if there is no value for the current day, and use the last SOFA score for this organ.

SOFA Points →	**0**	**1**	**2**	**3**	**4**	**Point Value**
1. *Respiration* PaO_2/FiO_2 mm Hg	☐ ≥ 400 or (extubated & no ABG[A])	☐ < 400	☐ < 300	☐ < 200 with respiratory support	☐ < 100 with respiratory support	☐
2. *Coagulation* Platelets x $10^3/mm^3$	☐ ≥ 150	☐ < 150	☐ < 100	☐ < 50	☐ < 20	☐
3. *Liver* Bilirubin, mg/dL	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 5.9	☐ 6.0 - 11.9	☐ ≥ 12.0 *or* MARS[B]	☐
4. *Cardiovascular* Hypotension	☐ MAP[C] ≥ 70 mm Hg, No hypotension	☐ MAP[C] < 70 mm Hg	☐ Dopamine ≤ 5* *or* Dobutamine (any dose)	☐ Dopamine > 5* *or* Epinephrine ≤ 0.1* *or* Norepinephrine ≤ 0.1* *or* Vasopressin	☐ Dopamine > 15* *or* Epinephrine > 0.1* *or* Norepinephrine > 0.1* *or* CAD[D]	☐
5. *Central Nervous System* Glasgow coma score (GCS)	☐ 15	☐ 13 - 14	☐ 10 - 12	☐ 6 - 9 *or* ICP	☐ < 6	☐
6. *Renal* Creatinine, mg/dL or urine output	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 3.4	☐ 3.5 - 4.9 *or* < 500 mL/day	☐ ≥ 5.0 *or* < 200 mL/day *or* dialysis	☐

* units = µg/kg/min

A. ABG: Arterial Blood Gas

B. MARS: Molecular Absorbent Recirculating System

C. MAP: Mean Arterial Pressure = 1/3 (Systolic Pressure - Diastolic Pressure) + Diastolic Pressure

D. CAD: Cardiac Assist Devices

GLND **SOFA SCORING WORKSHEET SOURCE DOCUMENT**

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Day 14 SOFA Score Worksheet

Mark ('X') the appropriate box for each category (1-6) row and record the corresponding SOFA point value, from the top column, in the box at the end of each row. Use the last lab value, blood gas, or assessment if there is no value for the current day, and use the last SOFA score for this organ.

SOFA Points →	**0**	**1**	**2**	**3**	**4**	**Point Value**
1. *Respiration* PaO_2/FiO_2 mm Hg	☐ ≥ 400 or (extubated & no ABG[A])	☐ < 400	☐ < 300	☐ < 200 with respiratory support	☐ < 100 with respiratory support	☐
2. *Coagulation* Platelets x $10^3/mm^3$	☐ ≥ 150	☐ < 150	☐ < 100	☐ < 50	☐ < 20	☐
3. *Liver* Bilirubin, mg/dL	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 5.9	☐ 6.0 - 11.9	☐ ≥ 12.0 *or* MARS[B]	☐
4. *Cardiovascular* Hypotension	☐ MAP[C] ≥ 70 mm Hg, No hypotension	☐ MAP[C] < 70 mm Hg	☐ Dopamine ≤ 5* *or* Dobutamine (any dose)	☐ Dopamine > 5* *or* Epinephrine ≤ 0.1* *or* Norepinephrine ≤ 0.1* *or* Vasopressin	☐ Dopamine > 15* *or* Epinephrine > 0.1* *or* Norepinephrine > 0.1* *or* CAD[D]	☐
5. *Central Nervous System* Glasgow coma score (GCS)	☐ 15	☐ 13 - 14	☐ 10 - 12	☐ 6 - 9 *or* ICP	☐ < 6	☐
6. *Renal* Creatinine, mg/dL or urine output	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 3.4	☐ 3.5 - 4.9 *or* < 500 mL/day	☐ ≥ 5.0 *or* < 200 mL/day *or* dialysis	☐

* units = µg/kg/min

A. ABG: Arterial Blood Gas

B. MARS: Molecular Absorbent Recirculating System

C. MAP: Mean Arterial Pressure = 1/3 (Systolic Pressure - Diastolic Pressure) + Diastolic Pressure

D. CAD: Cardiac Assist Devices

GLND **SOFA SCORING WORKSHEET SOURCE DOCUMENT**

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Day 15 SOFA Score Worksheet

Mark ('X') the appropriate box for each category (1-6) row and record the corresponding SOFA point value, from the top column, in the box at the end of each row. Use the last lab value, blood gas, or assessment if there is no value for the current day, and use the last SOFA score for this organ.

SOFA Points →	**0**	**1**	**2**	**3**	**4**	**Point Value**
1. *Respiration* PaO_2/FiO_2 mm Hg	☐ ≥ 400 or (extubated & no ABG[A])	☐ < 400	☐ < 300	☐ < 200 with respiratory support	☐ < 100 with respiratory support	☐
2. *Coagulation* Platelets x $10^3/mm^3$	☐ ≥ 150	☐ < 150	☐ < 100	☐ < 50	☐ < 20	☐
3. *Liver* Bilirubin, mg/dL	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 5.9	☐ 6.0 - 11.9	☐ ≥ 12.0 *or* MARS[B]	☐
4. *Cardiovascular* Hypotension	☐ MAP[C] ≥ 70 mm Hg, No hypotension	☐ MAP[C] < 70 mm Hg	☐ Dopamine ≤ 5* *or* Dobutamine (any dose)	☐ Dopamine > 5* *or* Epinephrine ≤ 0.1* *or* Norepinephrine ≤ 0.1* *or* Vasopressin	☐ Dopamine > 15* *or* Epinephrine > 0.1* *or* Norepinephrine > 0.1* *or* CAD[D]	☐
5. *Central Nervous System* Glasgow coma score (GCS)	☐ 15	☐ 13 - 14	☐ 10 - 12	☐ 6 - 9 *or* ICP	☐ < 6	☐
6. *Renal* Creatinine, mg/dL or urine output	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 3.4	☐ 3.5 - 4.9 *or* < 500 mL/day	☐ ≥ 5.0 *or* < 200 mL/day *or* dialysis	☐

* units = µg/kg/min

A. ABG: Arterial Blood Gas

B. MARS: Molecular Absorbent Recirculating System

C. MAP: Mean Arterial Pressure = 1/3 (Systolic Pressure - Diastolic Pressure) + Diastolic Pressure

D. CAD: Cardiac Assist Devices

GLND **SOFA SCORING WORKSHEET SOURCE DOCUMENT**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (F M L) Form Completed By (Initials): ☐☐☐ (F M L) Date Form Completed: ☐☐ (month) ☐☐ (day) ☐☐ (year)

Day 16 SOFA Score Worksheet

Mark ('X') the appropriate box for each category (1-6) row and record the corresponding SOFA point value, from the top column, in the box at the end of each row. Use the last lab value, blood gas, or assessment if there is no value for the current day, and use the last SOFA score for this organ.

SOFA Points →	**0**	**1**	**2**	**3**	**4**	**Point Value**
1. *Respiration* PaO_2/FiO_2 mm Hg	☐ ≥ 400 or (extubated & no ABG[A])	☐ < 400	☐ < 300	☐ < 200 with respiratory support	☐ < 100 with respiratory support	☐
2. *Coagulation* Platelets x $10^3/mm^3$	☐ ≥ 150	☐ < 150	☐ < 100	☐ < 50	☐ < 20	☐
3. *Liver* Bilirubin, mg/dL	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 5.9	☐ 6.0 - 11.9	☐ ≥ 12.0 *or* MARS[B]	☐
4. *Cardiovascular* Hypotension	☐ MAP[C] ≥ 70 mm Hg, No hypotension	☐ MAP[C] < 70 mm Hg	☐ Dopamine ≤ 5* *or* Dobutamine (any dose)	☐ Dopamine > 5* *or* Epinephrine ≤ 0.1* *or* Norepinephrine ≤ 0.1* *or* Vasopressin	☐ Dopamine > 15* *or* Epinephrine > 0.1* *or* Norepinephrine > 0.1* *or* CAD[D]	☐
5. *Central Nervous System* Glasgow coma score (GCS)	☐ 15	☐ 13 - 14	☐ 10 - 12	☐ 6 - 9 *or* ICP	☐ < 6	☐
6. *Renal* Creatinine, mg/dL or urine output	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 3.4	☐ 3.5 - 4.9 *or* < 500 mL/day	☐ ≥ 5.0 *or* < 200 mL/day *or* dialysis	☐

* units = µg/kg/min

A. ABG: Arterial Blood Gas

B. MARS: Molecular Absorbent Recirculating System

C. MAP: Mean Arterial Pressure = 1/3 (Systolic Pressure - Diastolic Pressure) + Diastolic Pressure

D. CAD: Cardiac Assist Devices

GLND **SOFA SCORING WORKSHEET SOURCE DOCUMENT**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (F M L) Form Completed By (Initials): ☐☐☐ (F M L) Date Form Completed: ☐☐ (month) ☐☐ (day) ☐☐ (year)

Day 17 SOFA Score Worksheet

Mark ('X') the appropriate box for each category (1-6) row and record the corresponding SOFA point value, from the top column, in the box at the end of each row. Use the last lab value, blood gas, or assessment if there is no value for the current day, and use the last SOFA score for this organ.

SOFA Points →	**0**	**1**	**2**	**3**	**4**	**Point Value**
1. *Respiration* PaO_2/FiO_2 mm Hg	☐ ≥ 400 or (extubated & no ABG[A])	☐ < 400	☐ < 300	☐ < 200 with respiratory support	☐ < 100 with respiratory support	☐
2. *Coagulation* Platelets x $10^3/mm^3$	☐ ≥ 150	☐ < 150	☐ < 100	☐ < 50	☐ < 20	☐
3. *Liver* Bilirubin, mg/dL	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 5.9	☐ 6.0 - 11.9	☐ ≥ 12.0 *or* MARS[B]	☐
4. *Cardiovascular* Hypotension	☐ MAP[C] ≥ 70 mm Hg, No hypotension	☐ MAP[C] < 70 mm Hg	☐ Dopamine ≤ 5* *or* Dobutamine (any dose)	☐ Dopamine > 5* *or* Epinephrine ≤ 0.1* *or* Norepinephrine ≤ 0.1* *or* Vasopressin	☐ Dopamine > 15* *or* Epinephrine > 0.1* *or* Norepinephrine > 0.1* *or* CAD[D]	☐
5. *Central Nervous System* Glasgow coma score (GCS)	☐ 15	☐ 13 - 14	☐ 10 - 12	☐ 6 - 9 *or* ICP	☐ < 6	☐
6. *Renal* Creatinine, mg/dL or urine output	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 3.4	☐ 3.5 - 4.9 *or* < 500 mL/day	☐ ≥ 5.0 *or* < 200 mL/day *or* dialysis	☐

* units = µg/kg/min

A. ABG: Arterial Blood Gas

B. MARS: Molecular Absorbent Recirculating System

C. MAP: Mean Arterial Pressure = 1/3 (Systolic Pressure - Diastolic Pressure) + Diastolic Pressure

D. CAD: Cardiac Assist Devices

GLND **SOFA SCORING WORKSHEET SOURCE DOCUMENT**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (F M L) Form Completed By (Initials): ☐☐☐ (F M L) Date Form Completed: ☐☐ (month) ☐☐ (day) ☐☐ (year)

Day 18 SOFA Score Worksheet

Mark ('X') the appropriate box for each category (1-6) row and record the corresponding SOFA point value, from the top column, in the box at the end of each row. Use the last lab value, blood gas, or assessment if there is no value for the current day, and use the last SOFA score for this organ.

SOFA Points →	**0**	**1**	**2**	**3**	**4**	**Point Value**
1. *Respiration* PaO_2/FiO_2 mm Hg	☐ ≥ 400 or (extubated & no ABG[A])	☐ < 400	☐ < 300	☐ < 200 with respiratory support	☐ < 100 with respiratory support	☐
2. *Coagulation* Platelets x $10^3/mm^3$	☐ ≥ 150	☐ < 150	☐ < 100	☐ < 50	☐ < 20	☐
3. *Liver* Bilirubin, mg/dL	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 5.9	☐ 6.0 - 11.9	☐ ≥ 12.0 *or* MARS[B]	☐
4. *Cardiovascular* Hypotension	☐ MAP[C] ≥ 70 mm Hg, No hypotension	☐ MAP[C] < 70 mm Hg	☐ Dopamine ≤ 5* *or* Dobutamine (any dose)	☐ Dopamine > 5* *or* Epinephrine ≤ 0.1* *or* Norepinephrine ≤ 0.1* *or* Vasopressin	☐ Dopamine > 15* *or* Epinephrine > 0.1* *or* Norepinephrine > 0.1* *or* CAD[D]	☐
5. *Central Nervous System* Glasgow coma score (GCS)	☐ 15	☐ 13 - 14	☐ 10 - 12	☐ 6 - 9 *or* ICP	☐ < 6	☐
6. *Renal* Creatinine, mg/dL or urine output	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 3.4	☐ 3.5 - 4.9 *or* < 500 mL/day	☐ ≥ 5.0 *or* < 200 mL/day *or* dialysis	☐

* units = µg/kg/min

A. ABG: Arterial Blood Gas

B. MARS: Molecular Absorbent Recirculating System

C. MAP: Mean Arterial Pressure = 1/3 (Systolic Pressure - Diastolic Pressure) + Diastolic Pressure

D. CAD: Cardiac Assist Devices

GLND **SOFA SCORING WORKSHEET SOURCE DOCUMENT**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (*F M L*) Form Completed By (Initials): ☐☐☐ (*F M L*) Date Form Completed: ☐☐ (*month*) ☐☐ (*day*) ☐☐ (*year*)

Day 19 SOFA Score Worksheet

Mark ('X') the appropriate box for each category (1-6) row and record the corresponding SOFA point value, from the top column, in the box at the end of each row. Use the last lab value, blood gas, or assessment if there is no value for the current day, and use the last SOFA score for this organ.

SOFA Points →	**0**	**1**	**2**	**3**	**4**	**Point Value**
1. *Respiration* PaO_2/FiO_2 mm Hg	☐ ≥ 400 or (extubated & no ABG[A])	☐ < 400	☐ < 300	☐ < 200 with respiratory support	☐ < 100 with respiratory support	☐
2. *Coagulation* Platelets x $10^3/mm^3$	☐ ≥ 150	☐ < 150	☐ < 100	☐ < 50	☐ < 20	☐
3. *Liver* Bilirubin, mg/dL	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 5.9	☐ 6.0 - 11.9	☐ ≥ 12.0 *or* MARS[B]	☐
4. *Cardiovascular* Hypotension	☐ MAP[C] ≥ 70 mm Hg, No hypotension	☐ MAP[C] < 70 mm Hg	☐ Dopamine ≤ 5* *or* Dobutamine (any dose)	☐ Dopamine > 5* *or* Epinephrine ≤ 0.1* *or* Norepinephrine ≤ 0.1* *or* Vasopressin	☐ Dopamine > 15* *or* Epinephrine > 0.1* *or* Norepinephrine > 0.1* *or* CAD[D]	☐
5. *Central Nervous System* Glasgow coma score (GCS)	☐ 15	☐ 13 - 14	☐ 10 - 12	☐ 6 - 9 *or* ICP	☐ < 6	☐
6. *Renal* Creatinine, mg/dL or urine output	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 3.4	☐ 3.5 - 4.9 *or* < 500 mL/day	☐ ≥ 5.0 *or* < 200 mL/day *or* dialysis	☐

* units = µg/kg/min

A. ABG: Arterial Blood Gas

B. MARS: Molecular Absorbent Recirculating System

C. MAP: Mean Arterial Pressure = 1/3 (Systolic Pressure - Diastolic Pressure) + Diastolic Pressure

D. CAD: Cardiac Assist Devices

GLND **SOFA SCORING WORKSHEET SOURCE DOCUMENT**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (F M L) Form Completed By (Initials): ☐☐☐ (F M L) Date Form Completed: ☐☐ (month) ☐☐ (day) ☐☐ (year)

Day 20 SOFA Score Worksheet

Mark ('X') the appropriate box for each category (1-6) row and record the corresponding SOFA point value, from the top column, in the box at the end of each row. Use the last lab value, blood gas, or assessment if there is no value for the current day, and use the last SOFA score for this organ.

SOFA Points →	**0**	**1**	**2**	**3**	**4**	**Point Value**
1. *Respiration* PaO_2/FiO_2 mm Hg	☐ ≥ 400 or (extubated & no ABG[A])	☐ < 400	☐ < 300	☐ < 200 with respiratory support	☐ < 100 with respiratory support	☐
2. *Coagulation* Platelets x $10^3/mm^3$	☐ ≥ 150	☐ < 150	☐ < 100	☐ < 50	☐ < 20	☐
3. *Liver* Bilirubin, mg/dL	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 5.9	☐ 6.0 - 11.9	☐ ≥ 12.0 *or* MARS[B]	☐
4. *Cardiovascular* Hypotension	☐ MAP[C] ≥ 70 mm Hg, No hypotension	☐ MAP[C] < 70 mm Hg	☐ Dopamine ≤ 5* *or* Dobutamine (any dose)	☐ Dopamine > 5* *or* Epinephrine ≤ 0.1* *or* Norepinephrine ≤ 0.1* *or* Vasopressin	☐ Dopamine > 15* *or* Epinephrine > 0.1* *or* Norepinephrine > 0.1* *or* CAD[D]	☐
5. *Central Nervous System* Glasgow coma score (GCS)	☐ 15	☐ 13 - 14	☐ 10 - 12	☐ 6 - 9 *or* ICP	☐ < 6	☐
6. *Renal* Creatinine, mg/dL or urine output	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 3.4	☐ 3.5 - 4.9 *or* < 500 mL/day	☐ ≥ 5.0 *or* < 200 mL/day *or* dialysis	☐

* units = µg/kg/min

A. ABG: Arterial Blood Gas

B. MARS: Molecular Absorbent Recirculating System

C. MAP: Mean Arterial Pressure = 1/3 (Systolic Pressure - Diastolic Pressure) + Diastolic Pressure

D. CAD: Cardiac Assist Devices

GLND **SOFA SCORING WORKSHEET SOURCE DOCUMENT**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (F M L) Form Completed By (Initials): ☐☐☐ (F M L) Date Form Completed: ☐☐ (month) ☐☐ (day) ☐☐ (year)

Day 21 SOFA Score Worksheet

Mark ('X') the appropriate box for each category (1-6) row and record the corresponding SOFA point value, from the top column, in the box at the end of each row. Use the last lab value, blood gas, or assessment if there is no value for the current day, and use the last SOFA score for this organ.

SOFA Points →	**0**	**1**	**2**	**3**	**4**	**Point Value**
1. *Respiration* PaO_2/FiO_2 mm Hg	☐ ≥ 400 or (extubated & no ABG[A])	☐ < 400	☐ < 300	☐ < 200 with respiratory support	☐ < 100 with respiratory support	☐
2. *Coagulation* Platelets x $10^3/mm^3$	☐ ≥ 150	☐ < 150	☐ < 100	☐ < 50	☐ < 20	☐
3. *Liver* Bilirubin, mg/dL	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 5.9	☐ 6.0 - 11.9	☐ ≥ 12.0 *or* MARS[B]	☐
4. *Cardiovascular* Hypotension	☐ MAP[C] ≥ 70 mm Hg, No hypotension	☐ MAP[C] < 70 mm Hg	☐ Dopamine ≤ 5* *or* Dobutamine (any dose)	☐ Dopamine > 5* *or* Epinephrine ≤ 0.1* *or* Norepinephrine ≤ 0.1* *or* Vasopressin	☐ Dopamine > 15* *or* Epinephrine > 0.1* *or* Norepinephrine > 0.1* *or* CAD[D]	☐
5. *Central Nervous System* Glasgow coma score (GCS)	☐ 15	☐ 13 - 14	☐ 10 - 12	☐ 6 - 9 *or* ICP	☐ < 6	☐
6. *Renal* Creatinine, mg/dL or urine output	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 3.4	☐ 3.5 - 4.9 *or* < 500 mL/day	☐ ≥ 5.0 *or* < 200 mL/day *or* dialysis	☐

* units = µg/kg/min

A. ABG: Arterial Blood Gas

B. MARS: Molecular Absorbent Recirculating System

C. MAP: Mean Arterial Pressure = 1/3 (Systolic Pressure - Diastolic Pressure) + Diastolic Pressure

D. CAD: Cardiac Assist Devices

GLND **SOFA SCORING WORKSHEET SOURCE DOCUMENT**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (F M L) Form Completed By (Initials): ☐☐☐ (F M L) Date Form Completed: ☐☐ (month) ☐☐ (day) ☐☐ (year)

Day 22 SOFA Score Worksheet

Mark ('X') the appropriate box for each category (1-6) row and record the corresponding SOFA point value, from the top column, in the box at the end of each row. Use the last lab value, blood gas, or assessment if there is no value for the current day, and use the last SOFA score for this organ.

SOFA Points →	**0**	**1**	**2**	**3**	**4**	**Point Value**
1. *Respiration* PaO_2/FiO_2 mm Hg	☐ ≥ 400 or (extubated & no ABG[A])	☐ < 400	☐ < 300	☐ < 200 with respiratory support	☐ < 100 with respiratory support	☐
2. *Coagulation* Platelets x $10^3/mm^3$	☐ ≥ 150	☐ < 150	☐ < 100	☐ < 50	☐ < 20	☐
3. *Liver* Bilirubin, mg/dL	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 5.9	☐ 6.0 - 11.9	☐ ≥ 12.0 *or* MARS[B]	☐
4. *Cardiovascular* Hypotension	☐ MAP[C] ≥ 70 mm Hg, No hypotension	☐ MAP[C] < 70 mm Hg	☐ Dopamine ≤ 5* *or* Dobutamine (any dose)	☐ Dopamine > 5* *or* Epinephrine ≤ 0.1* *or* Norepinephrine ≤ 0.1* *or* Vasopressin	☐ Dopamine > 15* *or* Epinephrine > 0.1* *or* Norepinephrine > 0.1* *or* CAD[D]	☐
5. *Central Nervous System* Glasgow coma score (GCS)	☐ 15	☐ 13 - 14	☐ 10 - 12	☐ 6 - 9 *or* ICP	☐ < 6	☐
6. *Renal* Creatinine, mg/dL or urine output	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 3.4	☐ 3.5 - 4.9 *or* < 500 mL/day	☐ ≥ 5.0 *or* < 200 mL/day *or* dialysis	☐

* units = µg/kg/min

A. ABG: Arterial Blood Gas

B. MARS: Molecular Absorbent Recirculating System

C. MAP: Mean Arterial Pressure = 1/3 (Systolic Pressure - Diastolic Pressure) + Diastolic Pressure

D. CAD: Cardiac Assist Devices

GLND **SOFA SCORING WORKSHEET SOURCE DOCUMENT**

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Day 23 SOFA Score Worksheet

Mark ('X') the appropriate box for each category (1-6) row and record the corresponding SOFA point value, from the top column, in the box at the end of each row. Use the last lab value, blood gas, or assessment if there is no value for the current day, and use the last SOFA score for this organ.

SOFA Points →	**0**	**1**	**2**	**3**	**4**	**Point Value**
1. *Respiration* PaO_2/FiO_2 mm Hg	☐ ≥ 400 or (extubated & no ABG[A])	☐ < 400	☐ < 300	☐ < 200 with respiratory support	☐ < 100 with respiratory support	☐
2. *Coagulation* Platelets x $10^3/mm^3$	☐ ≥ 150	☐ < 150	☐ < 100	☐ < 50	☐ < 20	☐
3. *Liver* Bilirubin, mg/dL	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 5.9	☐ 6.0 - 11.9	☐ ≥ 12.0 *or* MARS[B]	☐
4. *Cardiovascular* Hypotension	☐ MAP[C] ≥ 70 mm Hg, No hypotension	☐ MAP[C] < 70 mm Hg	☐ Dopamine ≤ 5* *or* Dobutamine (any dose)	☐ Dopamine > 5* *or* Epinephrine ≤ 0.1* *or* Norepinephrine ≤ 0.1* *or* Vasopressin	☐ Dopamine > 15* *or* Epinephrine > 0.1* *or* Norepinephrine > 0.1* *or* CAD[D]	☐
5. *Central Nervous System* Glasgow coma score (GCS)	☐ 15	☐ 13 - 14	☐ 10 - 12	☐ 6 - 9 *or* ICP	☐ < 6	☐
6. *Renal* Creatinine, mg/dL or urine output	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 3.4	☐ 3.5 - 4.9 *or* < 500 mL/day	☐ ≥ 5.0 *or* < 200 mL/day *or* dialysis	☐

* units = µg/kg/min

A. ABG: Arterial Blood Gas

B. MARS: Molecular Absorbent Recirculating System

C. MAP: Mean Arterial Pressure = 1/3 (Systolic Pressure - Diastolic Pressure) + Diastolic Pressure

D. CAD: Cardiac Assist Devices

GLND **SOFA SCORING WORKSHEET SOURCE DOCUMENT**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (F M L) Form Completed By (Initials): ☐☐☐ (F M L) Date Form Completed: ☐☐ (month) ☐☐ (day) ☐☐ (year)

Day 24 SOFA Score Worksheet

Mark ('X') the appropriate box for each category (1-6) row and record the corresponding SOFA point value, from the top column, in the box at the end of each row. Use the last lab value, blood gas, or assessment if there is no value for the current day, and use the last SOFA score for this organ.

SOFA Points →	**0**	**1**	**2**	**3**	**4**	**Point Value**
1. *Respiration* PaO_2/FiO_2 mm Hg	☐ ≥ 400 or (extubated & no ABG[A])	☐ < 400	☐ < 300	☐ < 200 with respiratory support	☐ < 100 with respiratory support	☐
2. *Coagulation* Platelets x $10^3/mm^3$	☐ ≥ 150	☐ < 150	☐ < 100	☐ < 50	☐ < 20	☐
3. *Liver* Bilirubin, mg/dL	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 5.9	☐ 6.0 - 11.9	☐ ≥ 12.0 *or* MARS[B]	☐
4. *Cardiovascular* Hypotension	☐ MAP[C] ≥ 70 mm Hg, No hypotension	☐ MAP[C] < 70 mm Hg	☐ Dopamine ≤ 5* *or* Dobutamine (any dose)	☐ Dopamine > 5* *or* Epinephrine ≤ 0.1* *or* Norepinephrine ≤ 0.1* *or* Vasopressin	☐ Dopamine > 15* *or* Epinephrine > 0.1* *or* Norepinephrine > 0.1* *or* CAD[D]	☐
5. *Central Nervous System* Glasgow coma score (GCS)	☐ 15	☐ 13 - 14	☐ 10 - 12	☐ 6 - 9 *or* ICP	☐ < 6	☐
6. *Renal* Creatinine, mg/dL or urine output	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 3.4	☐ 3.5 - 4.9 *or* < 500 mL/day	☐ ≥ 5.0 *or* < 200 mL/day *or* dialysis	☐

* units = µg/kg/min

A. ABG: Arterial Blood Gas

B. MARS: Molecular Absorbent Recirculating System

C. MAP: Mean Arterial Pressure = 1/3 (Systolic Pressure - Diastolic Pressure) + Diastolic Pressure

D. CAD: Cardiac Assist Devices

GLND **SOFA SCORING WORKSHEET SOURCE DOCUMENT**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (F M L) Form Completed By (Initials): ☐☐☐ (F M L) Date Form Completed: ☐☐ (month) ☐☐ (day) ☐☐ (year)

Day 25 SOFA Score Worksheet

Mark ('X') the appropriate box for each category (1-6) row and record the corresponding SOFA point value, from the top column, in the box at the end of each row. Use the last lab value, blood gas, or assessment if there is no value for the current day, and use the last SOFA score for this organ.

SOFA Points →	**0**	**1**	**2**	**3**	**4**	**Point Value**
1. *Respiration* PaO_2/FiO_2 mm Hg	☐ ≥ 400 or (extubated & no ABG[A])	☐ < 400	☐ < 300	☐ < 200 with respiratory support	☐ < 100 with respiratory support	☐
2. *Coagulation* Platelets x $10^3/mm^3$	☐ ≥ 150	☐ < 150	☐ < 100	☐ < 50	☐ < 20	☐
3. *Liver* Bilirubin, mg/dL	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 5.9	☐ 6.0 - 11.9	☐ ≥ 12.0 *or* MARS[B]	☐
4. *Cardiovascular* Hypotension	☐ MAP[C] ≥ 70 mm Hg, No hypotension	☐ MAP[C] < 70 mm Hg	☐ Dopamine ≤ 5* *or* Dobutamine (any dose)	☐ Dopamine > 5* *or* Epinephrine ≤ 0.1* *or* Norepinephrine ≤ 0.1* *or* Vasopressin	☐ Dopamine > 15* *or* Epinephrine > 0.1* *or* Norepinephrine > 0.1* *or* CAD[D]	☐
5. *Central Nervous System* Glasgow coma score (GCS)	☐ 15	☐ 13 - 14	☐ 10 - 12	☐ 6 - 9 *or* ICP	☐ < 6	☐
6. *Renal* Creatinine, mg/dL or urine output	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 3.4	☐ 3.5 - 4.9 *or* < 500 mL/day	☐ ≥ 5.0 *or* < 200 mL/day *or* dialysis	☐

* units = µg/kg/min

A. ABG: Arterial Blood Gas

B. MARS: Molecular Absorbent Recirculating System

C. MAP: Mean Arterial Pressure = 1/3 (Systolic Pressure - Diastolic Pressure) + Diastolic Pressure

D. CAD: Cardiac Assist Devices

GLND **SOFA SCORING WORKSHEET SOURCE DOCUMENT**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (F M L) Form Completed By (Initials): ☐☐☐ (F M L) Date Form Completed: ☐☐ (month) ☐☐ (day) ☐☐ (year)

Day 26 SOFA Score Worksheet

Mark ('X') the appropriate box for each category (1-6) row and record the corresponding SOFA point value, from the top column, in the box at the end of each row. Use the last lab value, blood gas, or assessment if there is no value for the current day, and use the last SOFA score for this organ.

SOFA Points →	**0**	**1**	**2**	**3**	**4**	**Point Value**
1. *Respiration* PaO_2/FiO_2 mm Hg	☐ ≥ 400 or (extubated & no ABG[A])	☐ < 400	☐ < 300	☐ < 200 with respiratory support	☐ < 100 with respiratory support	☐
2. *Coagulation* Platelets x $10^3/mm^3$	☐ ≥ 150	☐ < 150	☐ < 100	☐ < 50	☐ < 20	☐
3. *Liver* Bilirubin, mg/dL	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 5.9	☐ 6.0 - 11.9	☐ ≥ 12.0 *or* MARS[B]	☐
4. *Cardiovascular* Hypotension	☐ MAP[C] ≥ 70 mm Hg, No hypotension	☐ MAP[C] < 70 mm Hg	☐ Dopamine ≤ 5* *or* Dobutamine (any dose)	☐ Dopamine > 5* *or* Epinephrine ≤ 0.1* *or* Norepinephrine ≤ 0.1* *or* Vasopressin	☐ Dopamine > 15* *or* Epinephrine > 0.1* *or* Norepinephrine > 0.1* *or* CAD[D]	☐
5. *Central Nervous System* Glasgow coma score (GCS)	☐ 15	☐ 13 - 14	☐ 10 - 12	☐ 6 - 9 *or* ICP	☐ < 6	☐
6. *Renal* Creatinine, mg/dL or urine output	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 3.4	☐ 3.5 - 4.9 *or* < 500 mL/day	☐ ≥ 5.0 *or* < 200 mL/day *or* dialysis	☐

* units = µg/kg/min

A. ABG: Arterial Blood Gas

B. MARS: Molecular Absorbent Recirculating System

C. MAP: Mean Arterial Pressure = 1/3 (Systolic Pressure - Diastolic Pressure) + Diastolic Pressure

D. CAD: Cardiac Assist Devices

GLND **SOFA SCORING WORKSHEET SOURCE DOCUMENT**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (F M L) Form Completed By (Initials): ☐☐☐ (F M L) Date Form Completed: ☐☐ (month) ☐☐ (day) ☐☐ (year)

Day 27 SOFA Score Worksheet

Mark ('X') the appropriate box for each category (1-6) row and record the corresponding SOFA point value, from the top column, in the box at the end of each row. Use the last lab value, blood gas, or assessment if there is no value for the current day, and use the last SOFA score for this organ.

SOFA Points →	**0**	**1**	**2**	**3**	**4**	**Point Value**
1. *Respiration* PaO_2/FiO_2 mm Hg	☐ ≥ 400 or (extubated & no ABG[A])	☐ < 400	☐ < 300	☐ < 200 with respiratory support	☐ < 100 with respiratory support	☐
2. *Coagulation* Platelets x $10^3/mm^3$	☐ ≥ 150	☐ < 150	☐ < 100	☐ < 50	☐ < 20	☐
3. *Liver* Bilirubin, mg/dL	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 5.9	☐ 6.0 - 11.9	☐ ≥ 12.0 *or* MARS[B]	☐
4. *Cardiovascular* Hypotension	☐ MAP[C] ≥ 70 mm Hg, No hypotension	☐ MAP[C] < 70 mm Hg	☐ Dopamine ≤ 5* *or* Dobutamine (any dose)	☐ Dopamine > 5* *or* Epinephrine ≤ 0.1* *or* Norepinephrine ≤ 0.1* *or* Vasopressin	☐ Dopamine > 15* *or* Epinephrine > 0.1* *or* Norepinephrine > 0.1* *or* CAD[D]	☐
5. *Central Nervous System* Glasgow coma score (GCS)	☐ 15	☐ 13 - 14	☐ 10 - 12	☐ 6 - 9 *or* ICP	☐ < 6	☐
6. *Renal* Creatinine, mg/dL or urine output	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 3.4	☐ 3.5 - 4.9 *or* < 500 mL/day	☐ ≥ 5.0 *or* < 200 mL/day *or* dialysis	☐

* units = µg/kg/min

A. ABG: Arterial Blood Gas

B. MARS: Molecular Absorbent Recirculating System

C. MAP: Mean Arterial Pressure = 1/3 (Systolic Pressure - Diastolic Pressure) + Diastolic Pressure

D. CAD: Cardiac Assist Devices

GLND **SOFA SCORING WORKSHEET SOURCE DOCUMENT**

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (F M L) Form Completed By (Initials): ☐☐☐ (F M L) Date Form Completed: ☐☐ (month) ☐☐ (day) ☐☐ (year)

Day 28 SOFA Score Worksheet

Mark ('X') the appropriate box for each category (1-6) row and record the corresponding SOFA point value, from the top column, in the box at the end of each row. Use the last lab value, blood gas, or assessment if there is no value for the current day, and use the last SOFA score for this organ.

SOFA Points →	**0**	**1**	**2**	**3**	**4**	**Point Value**
1. *Respiration* PaO_2/FiO_2 mm Hg	☐ ≥ 400 or (extubated & no ABG[A])	☐ < 400	☐ < 300	☐ < 200 with respiratory support	☐ < 100 with respiratory support	☐
2. *Coagulation* Platelets x $10^3/mm^3$	☐ ≥ 150	☐ < 150	☐ < 100	☐ < 50	☐ < 20	☐
3. *Liver* Bilirubin, mg/dL	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 5.9	☐ 6.0 - 11.9	☐ ≥ 12.0 *or* MARS[B]	☐
4. *Cardiovascular* Hypotension	☐ MAP[C] ≥ 70 mm Hg, No hypotension	☐ MAP[C] < 70 mm Hg	☐ Dopamine ≤ 5* *or* Dobutamine (any dose)	☐ Dopamine > 5* *or* Epinephrine ≤ 0.1* *or* Norepinephrine ≤ 0.1* *or* Vasopressin	☐ Dopamine > 15* *or* Epinephrine > 0.1* *or* Norepinephrine > 0.1* *or* CAD[D]	☐
5. *Central Nervous System* Glasgow coma score (GCS)	☐ 15	☐ 13 - 14	☐ 10 - 12	☐ 6 - 9 *or* ICP	☐ < 6	☐
6. *Renal* Creatinine, mg/dL or urine output	☐ ≤ 1.1	☐ 1.2 - 1.9	☐ 2.0 - 3.4	☐ 3.5 - 4.9 *or* < 500 mL/day	☐ ≥ 5.0 *or* < 200 mL/day *or* dialysis	☐

* units = µg/kg/min

A. ABG: Arterial Blood Gas

B. MARS: Molecular Absorbent Recirculating System

C. MAP: Mean Arterial Pressure = 1/3 (Systolic Pressure - Diastolic Pressure) + Diastolic Pressure

D. CAD: Cardiac Assist Devices

SUSPECTED NOSOCOMIAL INFECTIONS LOG

TAB PAGE

All suspected nosocomial infections should be recorded, beginning with existing suspected infections at patient randomization. Fill out the Suspected Nosocomial Infections Log and Form for each determined nosocomial infection, or suspected but undetermined nosocomial infection. Refer to Section 9.1.b and Appendix 7 of the Study Manual of Operations for infection diagnosis procedures, definitions and codes. Appendix 7 is available on the following pages for your convenience.

Appendix 7. Procedures for Diagnosis of Nosocomial Infections

Adapted from:

1. Garner JS, Jarvis WR, Emori TG, Horan TC, Hughes JM. CDC definitions for nosocomial infections, 1988. Am J Infect Control 16:128-140; 1988.
2. Horan TC, Gaynes RP. Surveillance of nosocomial infections. In: Hospital Epidemiology and Infection Control, 3rd ed., Mayhall CG, editor. Philadelphia: Lippincott Williams & Wilkins,1659-1702; 2004.

Listing of Major and Specific Site Codes and Descriptions

1. UTI Urinary Tract Infection

a. SUTI Symptomatic urinary tract infection

b. ASB Asymptomatic bacteriuria

c. OUTI Other infections of the urinary tract

2. SSI Surgical Site Infection

a. SKIN Superficial incisional site, except after CBGB (coronary artery bypass graft with both chest and donor site incisions).

b. SKNC After CBGB, report SKNC for superficial incisional infection at chest incision site.

c. SKNL After CBGB, report SKNL for superficial incisional infection at vein donor site.

d. ST Deep incisional surgical site infection, except after CBGB.

e. STC After CBGB, report STC for deep incisional surgical site infection at chest incision site.

f. STL After CBGB, report STL for deep incisional surgical site infection at vein donor site.

g. ORGAN/SPACE SSI: Indicate specific site: BONE, BRST, CARD, DISC, EAR, EMET, ENDO, EYE, GIT, IAB, IC, JNT, LUNG, MED, MEN, ORAL, OREP, OUTI, SA, SINU, UR, VASC, VCUP (see abbreviation definitions below).

3. PNEU Pneumonia

a. PNU I (probable pneumonia)

b. PNU 2

c. PNU 3

4. BSI Bloodstream Infection

a. LCBI Laboratory-confirmed bloodstream infection

b. CSEP Clinical sepsis

5. BJ Bone and Joint Infection

a. BONE Osteomyelitis

b. JNT Joint or bursa

6. CNS Central Nervous System Infection

a. IC Intracranial infection

b. MEN Menitigitis or ventriculitis

c. SA Spinal abscess without meningitis

7. CVS Cardiovascular System Infection

a. VASC Arterial or venous infection

b. ENDO Endocarditis

c. CARD Myocarditis or pericarditis

d. MED Mediastinitis

8. EENT Eye, Ear, Nose, Throat, or Mouth Infection

a. EYE Eye other than conjunctivitis

b. ORAL Oral Cavity (mouth, tongue, or gums)

c. SINU Sinusitis

d. UR Upper respiratory tract, pharyngitis, laryngitis, epiglottitis

9. GI Gastrointestinal System Infection

a. GE Gastroenteritis

b. GIT Gastrointestinal (GI) tract

c. HEP Hepatitis

d. IAB Intra-abdominal, not specified elsewhere

10. LRI Lower Respiratory Tract Infection, Other Than Pneumonia

a. BRON Bronchitis, tracheobronchitis, tracheitis, without evidence of pneumonia

b. LUNG Other infections of the lower respiratory tract

11. SST Skin and Soft Tissue Infection

a. SKIN Skin

b. ST Soft tissue

c. DECU Decubitus ulcer

NOTE: AFTER SUBJECT ENTRY, DIAGNOSE AND RECORD IN THE CRFS ALL NOSOCOMIAL INFECTIONS PRESENT FROM THE DAY OF OPERATION UNTIL 48 HOURS AFTER STUDY PN IS INITIALLY ADMINISTERED. DO NOT DIAGNOSE NEW NOSOCOMINAL INFECTION FOR ENDPOINT ANALYSIS UNTIL 48 HOURS AFTER STUDY PN IS INITIALLY ADMINISTERED.

Diagnosis of relapsed previously diagnosed nosocomial infection versus a new nosocomial infection at the same body site: Reporting multiple episodes of specific nosocomial infections over time in a single subject (e.g. pneumonia) requires **all** of the following criteria (these will be monitored by the DCC):

1) At least a 2-week interval period between infections;

2) Evidence of resolution of the initial infection (e.g., defervescence after antimicrobial agents started, interval improvement in other clinical signs/symptoms);

3) Combination of new signs and symptoms and/or radiographic evidence or other diagnostic testing as outlined in the CDC guidelines; and

4) Completion of initial antibiotic course. In addition to these criteria, in the case of diagnosing new bloodstream infections (BSI) with the same organism, interval negative blood cultures are also required in order to diagnose a new BSI.

NOTES:

a) **ALL BSI WITH A DIFFERENT MICROORGANISM(s) CULTURED FROM BLOOD CULTURES DRAWN ON DIFFERENT DAYS ARE CODED AS A NEW BSI AND ARE NOT REQUIRED TO MEET THE ABOVE CRITERIA (E.G. CAN OCCUR WITHIN THE 2-WEEK INTERVAL ETC).**

b) **IF MULTIPLE MICORORGANISMS ARE CULTURED FROM BLOOD CULTURES DRAWN ON THE SAME DAY, CODE AS ONE BSI ONLY (POLYMICROBIAL BSI).**

CRITERIA REQUIRED TO DIAGNOSE INFECTION AT SPECIFIC BODY SITES

INFECTION SITE: Symptomatic urinary tract infection

CODE: UTI-SUTI

DEFINITION: A symptomatic urinary tract infection must meet at least one of the following criteria:

Criterion 1: Subject has at least one of the following signs or symptoms with no other recognized cause: fever (>38°C), urgency, frequency, dysuria, or suprapubic tenderness and subject has a positive urine culture, that is, ≥ 10^5 microorganisms per cm^3 of urine with no more than two species of microorganisms.

Criterion 2: Subject has at least two of the following signs or symptoms with no other recognized cause: fever (>38°C), urgency, frequency, dysuria, orsuprapubic tenderness and at least one of the following: a) Positive dipstick for leukocyte esterase and/or nitrate; b) Pyuria (urine specimen with ≥10 WBC/mm^3 or ≥ 3 WBC/high power field of unspun urine); c) Organisms seen on Gram stain of unspun urine; d) At least two urine cultures with repeated isolation of the same uropathogen (gram-negative bacteria or *S. saprophyticus*) with ≥ 10^5 colonies/mL in nonvoided specimens; e) ≤ 10^5 colonies/mL of a single uropathogen (gram-negative bacteria or *S. saprophyticus*) in a subject being treated with an effective antimicrobial agent for a urinary tract infection; f) Physician diagnosis of a urinary tract infection; g) Physician institutes appropriate therapy for a urinary tract infection.

COMMENTS:

- A positive culture of a urinary catheter tip is not an acceptable laboratory test to diagnose a urinary tract infection.
- Urine cultures must be obtained using appropriate technique, such as clean catch collection or catheterization.

INFECTION SITE: Asymptomatic bacteriuria

CODE: UTI-ASB

DEFINITION: An asymptoniatic bacteriuria must meet at least one of the following criteria:

Criterion 1: Subject has had an indwelling urinary catheter within 7 days before the culture and subject has a positive urine culture, that is, ≥ 10^5 microorganisms per cm^3 of urine with no more than two species of microorganisms and subject has *no* fever (>38°C), urgency, frequency, dysuria, or suprapubic tenderness.

Criterion 2: Subject has *not* had an indwelling urinary catheter within 7 days before the first positive culture and subject has had at least two positive urine cultures, that is, ≥ 10^5 microorganisms per cm^3 of urine with repeated isolation of the same microorganism and no more than two species of microorganisms and subject has no fever (>38°C), urgency, frequency, dysuria, or suprapubic tenderness.

COMMENTS:

- A positive culture of a urinary catheter tip is not an acceptable laboratory test to diagnose bacteriuria.
- Urine cultures must be obtained using appropriate technique, such as clean catch collection or catheterization.

INFECTION SITE: Other infections of the urinary tract (kidney, ureter, bladder, urethra, or tissues surrounding the retroperitoneal or perinephric spaces).

CODE: SUTI-OUTI

DEFINITION: Other infections of the urinary tract must meet at least one of the following criteria:

Criterion I: Subject has organisms isolated from culture of fluid (other than urine) or tissue from affected site.
Criterion 2: Subject has an abscess or other evidence of infection seen on direct examination, during a surgical operation, or during a histopathologic examination.

Criterion 3: Subject has at least *two* of the following signs or symptoms with no other recognized cause: fever (>38°C), localized pain, or localized tenderness at the involved site and at least one of the following: a)

Purulent drainage from affected site; b) Organisms cultured from blood that are compatible with suspected site of infection; c) Radiographic evidence of infection, for example, abnormal ultrasound, computed tomography (CT), magnetic resonance imaging (MRI), or radiolabel scan (gallium, technetium); d) Physician diagnosis of infection of the kidney, ureter, bladder, urethra, or tissues surrounding the retroperitoneal or perinephric space e) Physician institutes appropriate therapy for an infection of the kidney, ureter, bladder, urethra, or tissues surrounding the retroperitoneal or perinephric space.

INFECTION SITE: Surgical site infection (superficial incisional)

CODE: SSI-(SKIN) except following CBGB. For CBGB only, if infection is at chest site, use SKNC (skin-chest) or if at vein donor site, use SKNL (skin leg).

DEFINITION: A superficial SSI must meet the following criteria:

- Infection occurs within 30 days after the operative procedure and involves only skin and subcutaneous tissue of the incision.

and

- Subject has at least one of the following: a) Purulent drainage from the superficial incision; b) Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision; c) At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat, and superficial incision is deliberately opened by surgeon, unless incision is culture-negative; and d) Diagnosis of superficial incisional SSI by the surgeon or attending physician

REPORTING INSTRUCTIONS:

- Do not report a stitch abscess (minimal inflammation and discharge confined to the points ofsuture penetration) as an infection.

- Do not report a localized stab wound infection as a SSI, instead report as skin or soft tissue infection, depending on its depth.

- Report infected burn wound as SST-BURN.

- If the incisional site infection involves or extends into the fascial and muscle layers, report as a deep incisional SSI.

- Classify infection that involves both superficial and deep incision sites as deep incisional SSI.

- Report culture specimen from superficial incisions as ID (incisional drainage).

INFECTION SITE: Surgical site infection (deep incisional)

CODE:SSI-[ST (soft tissue)] except following CBGB. For CBGB only, if infection is at chest site, use SKNC (skin-chest) or if at vein donor site, use SKNL (skin leg).

DEFINITION: A deep incisional SSI must meet the following criteria:

- Infection occurs within 30 days after the operative procedure if no implant [A nonhuman-derived implantable foreign body (e.g., prosthetic heart valve, nonhuman vascular graft, mechanical heart, or hip prosthesis) that is permanently placed in a subject during surgery] is left in place or within I year if an implant is in place and the infection appears to be related to the operative procedure and involves deep soft tissues (e.g., fascial and muscle layers) of the incision and subject has at least one of the following: a) Purulent drainage from the deep incision but not from the organ/space component of the surgical site; b) A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the subject has at least one of the following signs or symptoms: fever (>38°C) or localized pain or tenderness, unless incision is culture-negative; c) An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination;d) Diagnosis of a deep incisional SSI by a surgeon or attending physician.

REPORTING INSTRUCTIONS

- Classify infection that involves both superficial and deep incision sites as deep incisional SSI.

- Report culture specimen from deep incisions as ID.

INFECTION SITE: Surgical site infection (organ/space)

CODE: SSI-(Specific site of organ/space)

DEFINITION: An organ/space SSI involves any part of the body, excluding the skin incision,fascia, or muscle layers, that is opened or manipulated during the operative procedure. Specific sites are assigned to organ/space SSI to further identify the location of the infection. Listed later are the specific sites that must be used to differentiate organ/space SSI. An example is appendectomy with subsequent subdiaphragmatic abscess, which would be reported as anorgan/space SSI at the intraabdominal specific site (SSI-IAB).

An organ/space SSI must meet the following criteria:

- Infection occurs within 30 days after the operative procedure if no implant is left in place or within 1 year if implant is in place and the infection appears to be related to the operative procedure;

  and

- Infection involves any part of the body, excluding the skin incision, fascia, or muscle layers, that is opened or manipulated during the operative procedure

  and

- Subject has at least one of the following: a) Purulent drainage from a drain that is placed through a stab wound into the organ/space; b0 Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space; c) An abscess or other evidence of infection involving the organ/space that is found on directexamination, during reoperation, or by histopathologic or radiologic examination; d) Diagnosis of an organ/space SSI by a surgeon or attending physician.

REPORTING INSTRUCTIONS

- Occasionally, an organ/space infection drains through the incision. Such infection generally does not involve reoperation and is considered a complication of the incision. Therefore, it is classified as a deep incisional SSI.

- Report culture specimen from organ/space as DD (deep drainage).

- The following are specific sites of an organ/space SSI: BONE Osteomyelitis; BRST Breast abscess or mastitis; CARD Myocarditis or pericarditis; DISC Disc space; EAR Ear, mastoid; EMET Endometritis ENDO Endocarditis; EYE Eye, other than conjunctivitis; GIT GI tract; IAB intraabdominal, not specified elsewhere; IC Intracranial, brain abscess or dura; JNT joint or bursa; LUNG Other infections of the lower respiratory tract; MED Mediastinitis; MEN Meningitis or ventriculitis; ORAL Oral cavity (mouth, tongue, or gums); OREP Other male or female; OUTI Other infections of the urinary tract; SA Spinal abscess without meningitis; SINU Sinusitis; UR Upper respiratory tract; VASC Arterial or venous infection.

INFECTION SITE: Mediastinitis

CODE: CVS-MED

DEFINITION; Mediastinitis must meet at least one of the following criteria:

Criterion 1: Subject has organisms cultured from mediastinal tissue or fluid obtained during a surgical operation or needle aspiration.

Criterion 2: Subject has evidence of mediastinitis seen during a surgical operation of histopathologic exainitiation.

Criterion 3: Subject has at least one of the following signs or symptoms with no other recognized cause: fever (>38°C), chest pain, or sternal instability and at least one of the following: a) Purulent discharge from mediastinal area; b) Organisms cultured from blood or discharge from mediastinal area; c) Mediastinal widening on x-ray.

REPORTING INSTRUCTION

- Report mediastinitis following cardiac surgery that is accompanied by osteomyelitis as SSI-MED rather than SSI BONE.

INFECTION SITE: Pneumonia

CRITERIA FOR DEFINING NOSOCOMIAL PNEUMONIA

General Comments Applicable to All Pneumonia Specific Site Criteria

1. Physician's diagnosis of pneumonia alone is *not* an acceptable criterion for nosocomial pneumonia.

2. Ventilator-associated pneumonia (i.e., pneumonia in persons who had a device to assist or control respiration continuously through a tracheostomy or by endotracheal intubation within the 48-hour period before the onset of infection) should be so designated when reporting pneumonia data.

3. When assessing a subject for presence of pneumonia, it is important to distinguish between changes in clinical status resulting from other conditions such as myocardial infarction, pulmonary embolism, respiratory distress syndrome, atelectasis, malignancy, chronic obstructive pulmonary disease, hyaline membrane disease, bronchopulmonary dysplasia, and so forth. Also, care must be taken when assessing intubated subjects to distinguish between tracheal colonization, upper respiratory tract infections (e.g., tracheobronchitis), and early onset pneumonia. Finally, it should be recognized that it may be difficult to determine nosocomial pneumonia in the elderly, infants, and immunocompromised subjects because such conditions may mask typical signs or symptoms associated with pneumonia. Alternate specific criteria for the elderly, infants and immunocompromised subjects have been included in this definition of nosocomial pneumonia.

4. Nosocomial pneumonia can be characterized by its onset: early or late. Early onset pneumonia occurs during the first 4 days of hospitalization and is often caused by Moraxella catarrhalis, H. influenzae, and S. pneumonide. Causative agents of late onset pneumonia are frequently gram-negative bacilli or Staphylococcus aureus, including methicillin-resistant S. aureus. Viruses (e.g., influenza A and B or respiratory syncytial virus) can cause early and late onset nosocomial pneumonia, whereas yeasts, fungi, legionellae, and Pneumocystis carinii are usually pathogens of late onset pneumonia.

5. Pneumonia resulting from gross aspiration (e.g., in the setting of intubation in the emergency room or operating room) is considered nosocomial if it meets any specific criteria and was not clearly present or incubating at the time of admission to the hospital.

6. Multiple episodes of nosocomial pneumonia may occur in critically ill subjects with lengthy hospital stays. When determining whether to report multiple episodes of nosocomial pneumonia in a single subject, look for evidence of resolution of the initial infection. The addition of or change in pathogen alone is not indicative of a new episode of pneumonia. The combination of new signs and symptoms and radiographic evidence or other diagnostic testing is required (see above guidelines).

7. Positive Gram stain for bacteria and positive KOH mount for elastin fibers and/or fungal hyphae from appropriately collected sputum specimens are important clues that point toward theetiology of the infection. However, sputum samples are frequently contaminated with airway colonizers and,therefore, must be

interpreted cautiously. In particular, Candida is commonly seen on stain or culture but infrequently causes nosocomial pneumonia.

Abbreviations

BAL-bronchoalveolar lavage

EIA-enzyme immunoassay

FAMA-fluorescent-antibody staining of membrane antigen

IFA-immunofluorescent antibody

LRT-lower respiratory tract

PCR-polymerase chain reaction

PMN-polymorphonuclear leukocyte

RIA-radioimmunoassay

Reporting Instructions

- There is a hierarchy of specific site categories within the major site pneumonia. Even if a subject meets criteria for more than one specific site, report only one:
  - If a subject meets criteria for both PNUI and PNU2, report PNU2.
  - If a subject meets criteria for both PNU2 and PNU3, report PNU3.
  - If a subject meets criteria for both PNUI and PNU3, report PNU3.
- Report concurrent lower respiratory tract infection (e.g., abscess or empyema) and pneumonia with the same organism(s) as pneumonia.
- Report lung abscess or empyema without pneumonia as LUNG.
- Report acute bronchitis, tracheitis, tracheobronchitis, or bronchiolitis without pneumonia as BRON

PNEUMONIA ALGORITHMS

Major Site: Pneumonia (PNEU)

1. Site-Specific Algorithms for Clinically Defined (Probable) Pneumonia (Code =PNU1)

Radiology

Two or more serial chest radiographs with at least one of the following [1,2]: 1) New or progressive and persistent infiltrate; 2) Consolidation; 3) Cavitation (note: in subjects without underlying pulmonary or cardiac disease (e.g., respiratory distress syndrome, bronchopulmonary dysplasia, pulmonary edema, or chronic obstructive pulmonary disease), *one* definitive chest radiograph is acceptable.

and

Signs/symptoms/laboratory

FOR ANY SUBJECT, at least one of the following:

- Fever (>38º C or >100.4º F) with no other recognized cause
- Leukopenia (<4,000 WBC/mm^3) *or* leukocytosis (≥ 12,000 WBC/mm^3)
- FOR ADULTS ≥70 YEARS OLD, altered mental status with no other recognized cause and at least two of the following:
- New onset of purulent sputum[3], or change in character of sputum[4], or increased respiratorysecretions, or increased suctioning requirements.

- New onset or worsening cough, or dyspnea, or tachypnea[5]

-Rales[6] or bronchial breath sounds

- Worsening gas exchange (e.g., O_2 desaturations [e.g.,Pa02/FiO_2 ≤240][7], increased oxygen requirements, or increased ventilation demand).

2. Specific Site Algorithms for Pneumonia with Common Bacterial or Filamentous Fungal Pathogens and Specific Laboratory Findings (Code=PNU2)

Radiology

Two or more serial chest radiographs with at least one of the following [1,2]: 1) New or progressive and persistent infiltrate; 2) Consolidation; 3) Cavitation (note: in subjects without underlying pulmonary or cardiac disease (e.g., respiratory distress syndrome, bronchopulmonary dysplasia, pulmonary edema, or chronic obstructive pulmonary disease), *one* definitive chest radiograph is acceptable.

and

Signs/symptoms

At least one of the following:

- Fever (>38º C or >100.4º F) with no other recognized cause

- Leukopenia (<4,000 WBC/mm^3) *or* leukocytosis (≥ 12,000 WBC/mm^3)

- FOR ADULTS ≥70 YEARS OLD, altered mental status with no other recognized cause and at least two of the following:

- New onset of purulent sputum[3], or change in character of sputum[4], or increased respiratorysecretions, or increased suctioning requirements.

- New onset or worsening cough, or dyspnea, or tachypnea[5]

-Rales[6] or bronchial breath sounds

- Worsening gas exchange (e.g., O_2 desaturations [e.g.,Pa02/FiO_2 ≤240][7], increased oxygen requirements, or increased ventilation demand).

and

Laboratory

At least one of the following:

- Positive growth in blood culture [8] not related to another source of infection

- Positive growth in culture of pleural fluid

- Positive quantitative culture [9] from minimally contaminated LRT specimen (e.g., BAL or protected specimen brushing)

- ≥5% BAL-obtained cells contain intracellular bacteria on direct microscopic exam (e.g.,Gram stain)

- Histopathologic exam shows at least one of the following evidences of pneumonia: 1) Abscess formation or foci of consolidation with intense PMN accumulation in bronchioles and alveoli; 2) Positive quantitative culture[9] of lung parenchyma or 3) Evidence of lung parenchyma invasion by fungal hyphae or pseudohyphae.

3. Specific Site Algorithms for Pneumonia with Viral, Legionella,Chlamydia, Mycoplasma, and Other Uncommon Pathogens and Specific Laboratory Findings (Code=PNU2)

Radiology

Two or more serial chest radiographs with at least one of the following [1,2]: 1) New or progressive and persistent infiltrate; 2) Consolidation; 3) Cavitation (note: in subjects without underlying pulmonary or cardiac disease (e.g., respiratory distress syndrome, bronchopulmonary dysplasia, pulmonary edema, or chronic obstructive pulmonary disease), *one* definitive chest radiograph is acceptable.

and

Signs/symptoms

At least one of the following:

- Fever (>38º C or >100.4º F) with no other recognized cause

- Leukopenia (<4,000 WBC/mm^3) *or* leukocytosis (≥ 12,000 WBC/mm^3)

- FOR ADULTS ≥70 YEARS OLD, altered mental status with no other recognized cause and at least two of the following:

- New onset of purulent sputum[3], or change in character of sputum[4], or increased respiratorysecretions, or increased suctioning requirements.

- New onset or worsening cough, or dyspnea, or tachypnea[5]

-Rales[6] or bronchial breath sounds

- Worsening gas exchange (e.g., O_2 desaturations [e.g.,Pa02/FiO_2 ≤240][7], increased oxygen requirements, or increased ventilation demand).

and

Laboratory

At least one of the following[10-12]:

- Positive culture of virus or Chlamydia from respiratory secretions

- Positive detection of viral antigen or antibody from respiratory secretions (e.g., EIA, FAMA, shell vial assay, PCR)

- Fourfold rise in paired sera (IgG) for pathogen (e.g., influenza viruses, Chlamydia)

- Positive PCR for Chlamydia or Mycoplasma

- Positive micro-IF test for Chlamydia

- Positive culture or visualization by micro-IF of *Legionella spp*. from respiratory secretions or tissue

- Detection of *Legionella pneumophila* serogroup 1 antigens in urine by RIA or EIA

- Fourfold rise in *L. pneumophila* serogroup I antibody titer to ≥ 1:128 in paired acute and convalescent sera by indirect IFA

4. Specific Site Algorithm for Pneumonia in Immunocompromised Subjects (Code=PNU3)

Radiology

Two or more serial chest radiographs with at least one of the following [1,2]: 1) New or progressive and persistent infiltrate; 2) Consolidation; 3) Cavitation (note: in subjects without underlying pulmonary or cardiac disease (e.g., respiratory distress syndrome, bronchopulmonary dysplasia, pulmonary edema, or chronic obstructive pulmonary disease), *one* definitive chest radiograph is acceptable.

and

Signs/symptoms

Subject who is immuncompromised [13] has at least one of the following:

- Fever (>38º C or >100.4º F) with no other recognized cause

- Leukopenia (<4,000 WBC/mm^3) *or* leukocytosis (≥ 12,000 WBC/mm^3)

- FOR ADULTS ≥70 YEARS OLD, altered mental status with no other recognized cause and at least two of the following:

- New onset of purulent sputum[3], or change in character of sputum[4], or increased respiratorysecretions, or increased suctioning requirements.

- New onset or worsening cough, or dyspnea, or tachypnea[5]

-Rales[6] or bronchial breath sounds

- Worsening gas exchange (e.g., O_2 desaturations [e.g.,Pa02/FiO_2 ≤240][7], increased oxygen requirements, or increased ventilation demand).

- Hemoptysis

- Pleuritic chest pain

and

Laboratory

At least one of the following:

- Matching positive blood and sputum cultures with *Candida Spp.*[14-15]

- Evidence of fungi or *Pneumocytis carinii* from minimally contaminated LRT specimen (e.g., BAL or protected specimen brushing) from one of the following: 1) Direct microscopic exam; or 2) Positive culture of fungi

-Any of the following from: LABORATORY CRITERIA DEFINED UNDER PNU2

FOOTNOTES

1. Occasionally, in nonventilated subjects, the diagnosis of nosocomial pneumonia may be quite clear on the basis of symptoms, signs, and a single definitive chest radiograph. However, in subjects with pulmonary or cardiac disease (e.g., interstitial lung disease or congestive heart failure), the diagnosis of pneumonia may be particularly difficult. Other noninfectious conditions (e.g., pulmonary edema from decompensated congestive heart failure) may simulate the presentation of pneumonia. In these more difficult cases, serial chest radiographs must be examined to help separate infectious from noninfectious pulmonary processes. To help confirm difficult cases, it may be useful to review radiographs on the day of diagnosis, 3 days prior to the diagnosis, and on days 2 and 7 after the diagnosis. Pneumonia may have rapid onset and progression but does not resolve quickly. Radiographic changes of pneumonia persist for several weeks. As a result, rapid radiograph resolution suggests that the subject does not have pneumonia but rather a noninfectious process such as atelectasis or congestive heart failure.

2. Note that there are many ways of describing the radiographic appearance of pneumonia. Examples include, but are not limited to, air-space disease, focal opacification, and patchy areas of increased density. Although perhaps not specifically delineated as pneumonia by the radiologist, in the appropriate clinical setting these alternative descriptive wordings should be seriously considered as potentially positive findings.

3. Purulent sputum is defined as secretions from the lungs, bronchi, or trachea that contain ≥ 25 neutrophils and ≤10 squamous epithelial cells per low power field (x 100). if your laboratory reports these data qualitatively (e.g., many WBCs or few squames), be sure their descriptors match this definition of purulent sputum. This laboratory confirmation is required because written clinical descriptions of purulence are highly variable.

4. A single notation of either purulent sputum or change in character of the sputum is not meaningful; repeated notations over a 24-hour period would be more indicative of the onset of an infectious process. Change in character of sputum refers to the color, consistency, odor, and quantity.

5. In adults, tachypnea is defined as respiration rate >25 breaths per minute.

6. Rales may be described as crackles.

7. This measure of arterial oxygenation is defined as the ratio of the arterial tension (Pa02) to the inspiratory fraction of oxygen (Fi02)

8. Care must be taken to determine the etiology of pneumonia in a subject with positive blood cultures and radiographic evidence of pneumonia, especially if the subject has invasive devices in place such as intravascular lines or an indwelling urinary catheter. In general, in an immunocompetent subject, blood cultures

positive for coagulase negative staphylococci, common skin contaminants, and yeasts will not be the etiologic agent of the pneumonia.

9. Refer to Table below for threshold values of bacteria from cultured specimens. An endotracheal aspirate is not a minimally contaminated specimen. Therefore, an endotracheal aspirate does not meet the laboratory criteria.

10. Once laboratory-confirmed cases of pneumonia due to respiratory syncytial virus (RSV), adenovirus, or influenza virus have been identified in a hospital, clinician's presumptive diagnosis of these pathogens in subsequent cases with similar clinical signs and symptoms is an acceptable criterion for presence of nosocomial infection.

11. Scant or watery sputum is commonly seen in adults with pneumonia due to viruses and Mycoplasma although sometimes the sputum may be mucopurulent.. Subjects with viral or mycoplasmal pneumonia may exhibit few signs or symptoms, even when significant infiltrates are present on radiographic exam.

12. Few bacteria may be seen on stains of respiratory secretions from subjects with pneumonia due to *Legionella spp, Mycoplasma*, or viruses.

13. Immunocompromised subjects include those with neutropenia (absolute neutrophil count < 500 mm^3), leukemia, lymphoma, HIV with CD4 count <200, or splenectomy; those who are in their transplant hospital stay; and those who are on cytotoxic chemotherapy, high dose steroids, or other immunosuppressives daily for >2 weeks [e.g., >40 mg of prednisone or its equivalent (>l60 mg hydrocortisone, >32 mg methylprednisolone, >6 mg dexamethasone, >200 mg cortisone)].

14. Blood and sputum specimens must be collected within 48 hours of each other.

15. Semiquantitative or nonquantitative cultures of sputum obtained by deep cough, induction, aspiration, or lavage are acceptable. If quantitative culture results are available, refer to algorithms that include such specific laboratory findings.

THRESHOLD VALUES FOR CULTURED SPECIMENS USED IN THE DIAGNOSIS OF PNEUMONIA

Specimen Collection/Technique	**Values**
Lung parenchyma [1]	≥10^4 CFU/g tissue
Bronchoscopically (B) obtained specimens	
Bronchoalveolar lavage	≥10^4 CFU/g CFU/mL
Protected specimen brushing	≥10^4 CFU/g CFU/mL
Nonbronchoscopically obtained (blind) specimens	≥10^4 CFU/g CFU/mL

1, open-lung biopsy specimens and immediate postmortem specimens obtained by transthoracic or transbronchial biopsy; CFU, colony-forming units; g, gram; mL, milliliter.

Definitions and Instructions for Criteria of Nosocomial Pneumonia

X-RAY:
In the subject who ***has underlying pulmonary disease*** such as respiratory distress syndrome, bronchopulmonary dysplasia, pulmonary edema, or chronic obstructive pulmonary disease, at least **two or more positive serial chest x-rays** are required and the subject must exhibit **one** or more of the listed symptoms [new or progressive and persistent infiltrate, consolidation, cavitation, or pneumatoceles (in subjects < 1 year)]. Check the tick box of the symptom(s) and proceed to the Signs and Symptoms section of the Flow Diagram.

In the subject who has ***no underlying pulmonary disease*** (see above), only **one positive chest x-ray** and **one** of the listed symptoms is sufficient to proceed to the Signs and Symptoms section. Check the tick box of the symptom(s) and proceed to the

Signs and Symptoms section of the Flow Diagram.

SIGNS AND SYMPTOMS:

Immunocompromised subject[1]: If the subject is immunocompromised and exhibits at least **one** of the signs or symptoms listed, check the appropriate tick boxes and proceed to the Laboratory section.

Non-immunocompromised subject: If the subject is not immunocompromised1 and exhibits at least **one** of the signs or symptoms listed in the top box (i.e., fever (> 38° C or 100.4°F) with no other recognized cause, leukopenia (< 4000 WBC/mm^3) or leukocytosis (> 12,000 WBC/mm^3), and/or for subjects > 70 years of age only, altered mental status with no other recognized cause), check the appropriate tick box(es) and proceed to the next set of signs and symptoms boxes.

a. If the non-immunocompromised subject meets at least **two** of the signs and symptoms criteria, check the appropriate tick boxes. Then proceed to the bottom of the Flow Diagram and check the tick box to indicate that this pneumonia meets the criteria for specific site PNU1.

b. If the non-immunocompromised subject has at least **one** of the signs and symptoms listed, check the appropriate tick boxes and proceed to the Laboratory section.

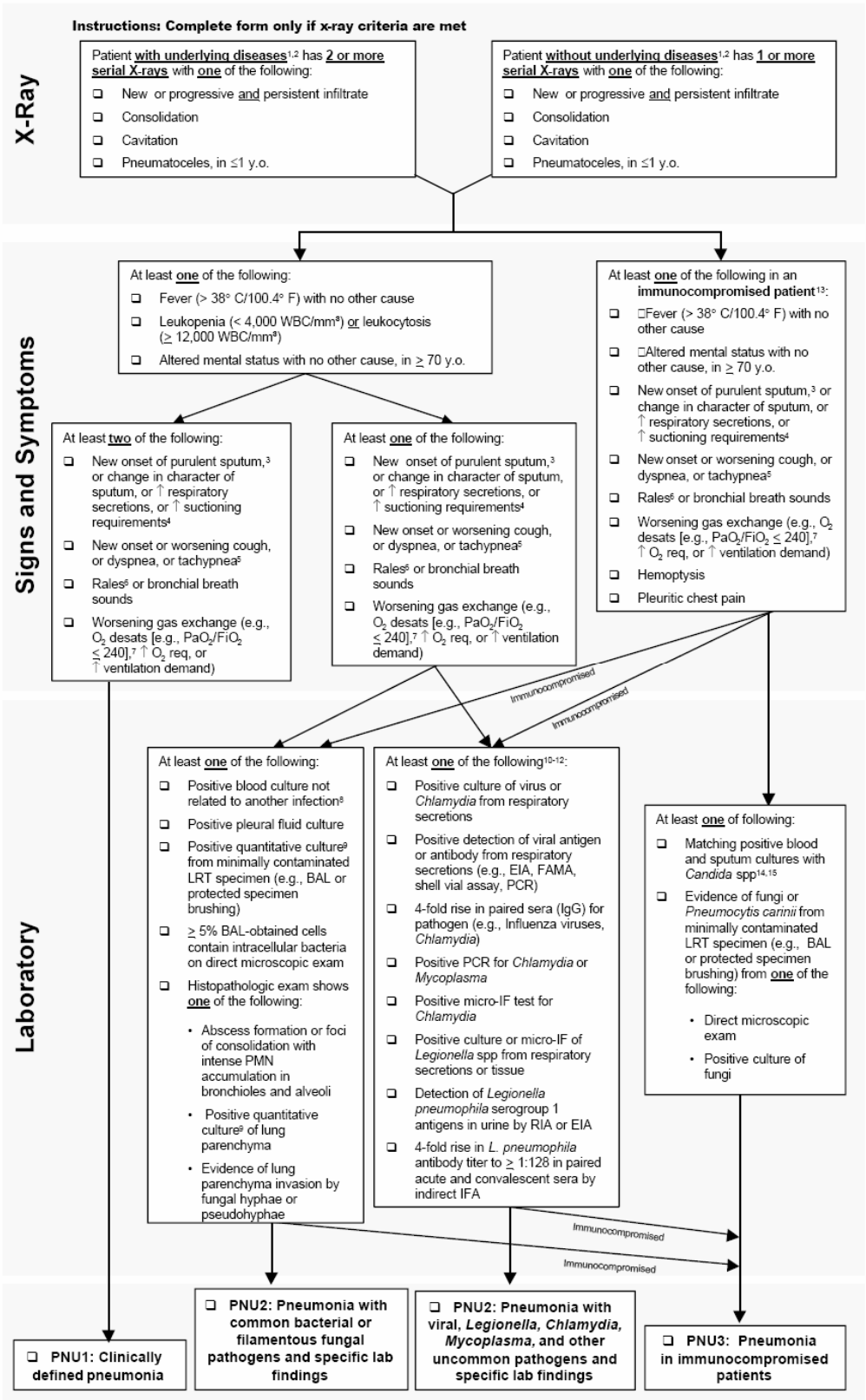
LABORATORY:

Immunocompromised subject1: If the subject is immunocompromised, check the results listed in any of the three Laboratory section boxes corresponding to the subject's positive laboratory tests. Then proceed to the bottom of the Flow Diagram and check the tick boxes indicating that this pneumonia meets the criteria for specific sites PNEU2 and/or PNU3.

Non-immunocompromised subject: If the subject is not immunocompromised, check the results listed in either the left or center boxes of the Laboratory section corresponding to the subject's positive laboratory tests. Then proceed to the bottom of the Flow Diagram and check the tick boxes indicating that this pneumonia meets one or both of the sets of criteria for specific site PNU2.

[1] IMMUNOCOMPROMISED SUBJECTS INCLUDE THOSE WITH:
a) neutropenia (absolute neutrophil count < 500/mm^3);
b) leukemia;
c) lymphoma;
d) HIV with CD4 count < 200;
e) patients whom have had a splenectomy;
f) those who are in their transplant hospital stay; and
g) those who are on cytotoxic chemotherapy, high dose steroids or other immunosuppressives daily for >2 weeks (e.g., > 40 mg of prednisone or its equivalent [> 160 mg hydrocortisone, > 32 mg methylprednisolone, > 6 mg dexamethasone, > 200 mg cortisone].

PNEUMONIA FLOW DIAGRAM



INFECTION SITE: Laboratory-confirmed bloodstream infection

CODE: BSI-LCBI

DEFINITION: Laboratory-confirmed bloodstream infection must meet at least one of the following criteria:

Criterion 1: Subject has a recognized pathogen cultured from one or more blood cultures and organism cultured from blood is not related to an infection at another site.

Criterion 2: Subject has at least one of the following signs or symptoms: fever (>38°C), chills, or hypotension and at least one of the following: a) Common skin contaminant (e.g., diphtheroids, *Bacillus* sp., *Propionibacterium* sp., coagulase-negative staphylococci) is cultured from two or more blood cultures drawn on separate occasions on the same day; b) Common skin contaminant (e.g., diphtheroids, *Bacillus* sp., *Propionibacterium* sp., coagulase-negative staphylococci) is cultured from at least one blood culture from a subject with an intravascular line, and the physician institutes appropriate antimicrobial therapy; c) Positive antigen test on blood (e.g., *Hemophilus influenzae*, *Streptococcus pneumoniae*, *Neisseria meningitidis*, or group B *Streptococcus*); and signs and symptoms and positive laboratory results are not related to an infection at another site.

REPORTING INSTRUCTIONS

- Report purulent phlebitis confirmed with a positive semiquantitative culture of a catheter tip, but with either negative or no blood culture, as CVS-VASC.
- Report organisms cultured from blood as BSI-LCBI when no other site of infection is evident.
- Pseudobacteremias are not nosocomial infections.

INFECTION SITE: Clinical sepsis

CODE: BSI-CSEP

DEFINITION: Clinical sepsis must meet the following criteria:

Criterion 1: Subject has at least one of the following clinical signs or symptoms with no other recognized cause: fever (>38°C), hypotension (systolic pressure ≤ 90 mm Hg), or oliguria (<20 cm^3/hr) and blood culture not done or no organisms or antigen detected in blood, and no apparent infection at another site and physician institutes treatment for sepsis.

REPORTING INSTRUCTIONS

- Report culture-positive infections of the bloodstream as BSI-LCBI.

INFECTION SITE: Osteomyelitis

CODE: BJ-BONE

DEFINITION: Osteomyelitis must meet at least one of the following criteria:

Criterion 1: Subject has organisms cultured from bone.

Criterion 2: Subject has evidence of osteomyelitis on direct examination of the bone during a surgical operation or histopathologic examination.

Criterion 3: Subject has at least two of the following signs or symptoms with no other recognized cause: fever (>38°C), localized swelling, tenderness, heat, or drainage at suspected site of bone infection, and at least one of the following: a) Organisms cultured from blood; b) Positive blood antigen test (e.g., *H. influenzae*, *S. pneumoniae*); c) Radiographic evidence of infection, for example, abnormal findings on x-ray, CT, MRI, radiolabeled scan (gallium, technetium, etc.).

INFECTION SITE: Joint or bursa

CODE: BJ-JNT

DEFINITION: Joint or bursa infections must meet at least one of the following criteria:

Criterion 1: Subject has organisms cultured from joint fluid or synovial biopsy.

Criterion 2: Subject has evidence of joint or bursa infection seen during a surgical operation or histopathologic examination.

Criterion 3: Subject has at least two of the following signs or symptoms with no other recognized cause: joint pain, swelling, tenderness, heat, evidence of effusion or limitation of motion and at least one of the following: a) Organisms and white blood cells seen on Gram stain of joint fluid; b) Positive antigen test on blood, urine, or joint fluid; c) Cellular profile and chemistries of joint fluid compatible with infection and not explained by an underlying rheumatologic disorder; d) Radiographic evidence of infection, for example, abnormal findings on x-ray, CT, MRI, radiolabel scan (gallium, technetium, etc.)

INFECTION SITE: Intracranial infection (brain abscess, subdural or epidural infection, encephalitis)

CODE: CNS-IC

DEFINITION: Intracranial infection must meet at least one of the following criteria:

Criterion 1: Subject has organisms cultured from brain tissue or dura.

Criterion 2: Subject has an abscess or evidence of intracranial infection seen during a surgical operation or histopathologic examination.

Criterion 3: Subject has at least two of the following signs or symptoms with no other recognized cause: headache, dizziness, fever (>38°C), localizing neurologic signs, changing levelof consciousness, or confusion and if diagnosis is made antemortem, physician institutes appropriate antimicrobial therapy and at least one of the following: a) Organisms seen on microscopic examination of brain or abscess tissue obtained by needle aspiration or by biopsy during a surgical operation or autopsy; b) Positive antigen test on blood or urine; c) Radiographic evidence of infection, for example, abnormal findings on ultrasound, CT, MRI,radionuclide brain scan, or arteriogram; or d) Diagnostic single antibody titer (IgM) or fourfold increase in paired sera (IgG) for pathogen.

REPORTING INSTRUCTIONS

- If meningitis and a brain abscess are present together, report the infection as IC.

INFECTION SITE: Meningitis or ventriculitis

CODE: CNS-MEN

DEFINITION: Meningitis or ventriculitis must meet at least one of the following criteria:

Criterion 1: Subject has organisms cultured from cerebrospinal fluid (CSF).

Criterion 2: Subject has at least one of the following signs of symptoms with no other recognized cause: fever (>38°C), headache, stiff neck, meningeal signs, cranial nerve signs, or irritability and if diagnosis is made antemortem, physician institutes appropriate antimicrobial therapy and at least one of the following: a) Increased white cells, elevated protein and/or decreased glucose in CSF; b) Organisms seen on Gram stain of CSF; c) Organisms cultured from blood; d) Positive antigen test of CSF, blood, or urine; e) Diagnostic single antibody titer (IgM) or fourfold increase in paired sera (IgG) for pathogen.

REPORTING INSTRUCTIONS

- Report meningoencephalitis as MEN.
- Report spinal abscess with meningitis as MEN.

INFECTION SITE: Spinal abscess without meningitis

CODE: CNS-SA

DEFINITION: An abscess of the spinal epidural or subdural space, without involvement of the CSF or adjacent bone structures, must meet at least one of the following criteria:

Criterion 1: Subject has organisms cultured from abscess in the spinal epidural or subdural space.

Criterion 2: Subject has an abscess in the spinal epidural or subdural space seen during a surgical operation or at autopsy of evidence of an abscess seen during a histopathologic examination.

Criterion 3: Subject has at least one of the following signs or symptoms with no other recognized cause: fever (>38°C), back pain, focal tenderness, radiculitis, paraparesis, or paraplegia and if diagnosis is made antemortem, physician institutes appropriate antimicrobial therapy and at least one of the following: a) Organisms cultured from blood; b) Radiographic evidence of a spinal abscess, for example, abnormal findings on myelography, ultrasound, CT, MRI, or other scans (gallium, technetium, etc.)

REPORTING INSTRUCTION

- Report spinal abscess with meningitis as MEN.

INFECTION SITE: Arterial or venous infection

CODE: CVS-VASC

DEFINITION: Arterial or venous infection must meet at least one of the following criteria:

Criterion 1: Subject has organisms cultured from arteries or veins removed during a surgical operation and blood culture not done or no organisms cultured from blood.

Criterion 2: Subject has evidence of arterial or venous infection seen during a surgical operation or histopathologic examination.

Criterion 3: Subject has at least one of the following signs or symptoms with no other recognized cause: fever (>38°C), pain, erythema, or heat at involved vascular site and more than 15 colonies cultured from intravascular cannula tip using semiquantitative culture method and blood culture not done or no organisms cultured from blood.

Criterion 4: Subject has purulent drainage at involved vascular site and blood culture not done or no organisms cultured from blood.

REPORTING INSTRUCTIONS

- Report infections of an arteriovenous graft, shunt, or fistula or intravascular cannulation site without organisms cultured from blood as CVS-VASC.
- Report intravascular infections with organisms cultured from the blood as BSI-LCBI

INFECTION SITE: Endocarditis involving either a natural or prosthetic heart valve

CODE: CVS-ENDO

DEFINITION: Endocarditis of a natural or prosthetic heart valve must meet at least one of the following criteria:

Criterion 1: Subject has organisms cultured from valve or vegetation.

Criterion 2: Subject has two or more of the following signs or symptoms with no other recognized cause: fever (>38°C), new or changing murmur, embolic phenomena, skin manifestations (i.e., petechiae, splinter hemorrhages, painful subcutaneous nodules),congestive heart failure, or cardiac conduction abnormality and if diagnosis is made antemortem, physician institutes appropriate antimicrobial therapy and at least one of the following: a) Organisms cultured from two or more blood cultures; b) Organisms seen on Gram stain of valve when culture is negative or not done; c) Valvular vegetation seen during a surgical operation or autopsy; d)

Positive antigen test on blood or urine (e.g., *H. influenzae*, *S. pneumoniae, N. meningitidis*, or group B *Streptococcus*); e) Evidence of new vegetation seen on echocardiogram.

INFECTION SITE: Myocarditis or pericarditis

CODE: CVS-CARD

DEFINITION: Myocarditis or pericarditis must meet at least one of the following criteria:

Criterion 1: Subject has organisms cultured from pericardial tissue or fluid obtained by needle aspiration or during a surgical operation.

Criterion 2: Subject has at least two of the following signs or symptoms with no other recognized cause: fever (>38°C), chest pain, paradoxical pulse, or increased heart size and at least one of the following: a) Abnormal electrocardiogram (ECG) consistent with myocarditis or pericarditis; b) Positive antigen test on blood (e.g., *H. influenzae, S. pneumoniae*); c) Evidence of myocarditis or pericarditis on histologic examination of heart tissue; d) Fourfold rise in type-specific antibody with or without isolation of virus from pharynx or feces; e) Pericardial effusion identified by echocardiogram, CT, MRI, or angiography

COMMENT

- Most cases of postcardiac surgery or postmyocardial infarction pericarditis are not infectious.

INFECTION SITE: Eye, other than conjunctivitis

CODE: EENT-EYE

DEFINITION: An infection of the eye, other than conjunctivitis, must meet at least one of the following criteria:

Criterion 1: Subject has organisms cultured from anterior or posterior chamber of vitreous fluid.

Criterion 2: Subject has at least two of the following signs or symptoms with no other recognized cause: eye pain, visual disturbance, or hypopyon and at least one of the following: a) Physician's diagnosis of an eye infection; b) Positive antigen test on blood (e.g., *H. Influenzae, S. pneumoniae*); c) Organisms cultured from blood

INFECTION SITE: Oral cavity (mouth, tongue, or gums)

CODE: EENT-ORAL

DEFINITION: Oral cavity infections must meet at least one of the following criteria:

Criterion 1: Subject has organisms cultured from purulent material from tissues of oral cavity.

Criterion 2: Subject has an abscess or other evidence of oral cavity infection seen on direct examination,during a surgical operation, or during a histopathologic examination.

Criterion 3: Subject has at least one of the following signs or symptoms with no other recognized cause: abscess, ulceration, or raised white patches on inflamed mucosa, or plaques on oral mucosa and at least one of the following: a) Organisms seen on Gram stain; b) Positive potassium hydroxide (KOH) stain; c) Multinucleated giant cells seen on microscopic examination of mucosal scrapings; d) Positive antigen test on oral secretions; e) Diagnostic single antibody titer (IgM) or fourfold increase in paired sera (IgG) for pathogen; f) Physician diagnosis of infection and treatment with topical or oral antifungal therapy

REPORTING INSTRUCTION

- Report nosocomial primary herpes simplex infections of the oral cavity as ORAL; recurrent herpes infections are not nosocomial.

INFECTION SITE: Sinusitis

CODE: EENT-SINU

DEFINITION: Sinusitis must meet at least one of the following criteria:

Criterion 1: Subject has organisms cultured from purulent material obtained from sinus cavity.

Criterion 2: Subject has at least one of the following signs or symptoms with no other recognized cause: fever (>38°C), pain or tenderness over the involved sinus, headache, purulent exudates or nasal obstruction and at least one of the following: a) Positive transillumination; b) Positive radiographic examination.

INFECTION SITE: Upper respiratory tract, pharyngitis, laryngitis, epiglottitis

CODE: EENT-UR

DEFINITION: Upper respiratory tract infections must meet at least one the following criteria:

Criterion 1: Subject has at least two of the following signs or symptoms with no other recognized cause: fever (>38°C), erythema of pharynx, sore throat, cough, hoarseness, of purulent exudate in throat and at least one of the following: a) Organisms cultured from the specific site; b) Organisms cultured from blood; c) Positive antigen test on blood or respiratory secretions; d) Diagnostic single antibody titer (IgM) or fourfold increase in paired sera (IgG) for pathogen; e) Physician's diagnosis of an upper respiratory infection

Criterion 2: Subject has an abscess seen on direct examination during a surgical operation, or during a histopathologic examination.

INFECTION SITE: Gastroenteritis (*clostridium difficile*)

CODE: GI-GE

DEFINITION: Gastroenteritis must meet at least one of the following criteria:

Criterion 1: Subject has an acute onset of diarrhea (liquid stools for more than 12 hours) with or without vomiting or fever (>38°C) and no likely noninfectious cause (e.g., diagnostic tests, therapeutic regimen, acute exacerbation of a chronic condition, or psychologic stress).

and

Criterion 2: Subject has at a positive diagnostic test for *c. difficile* (positive specific toxin assay or colonoscopy/sigmoidoscopy evidence of pseudomembranes);

INFECTION SITE: GI tract (esophagus, stomach, small and large bowel, and rectum) excluding gastroenteritis and appendicitis

CODE: GI-GIT

DEFINITION: Gastrointestinal tract infections, excluding gastroenteritis and appendicitis, mustmeet at least one of the following criteria:

Criterion 1: Subject has an abscess or other evidence of infection seen during a surgicaloperation or histopathologic examination.

Criterion 2: Subject has at least two of the following signs or symptoms with no other recognized cause and compatible with infection of the organ or tissue involved: fever (>38°C), nausea, vomiting, abdominal pain, or tenderness and at least one of the following: a) Organisms cultured from drainage or tissue obtained during a surgical operation or endoscopy or from a surgically placed drain; b) Organisms seen on Gram or KOH stain or multinucleated giant cells seen on microscopic examination of drainage or tissue obtained during a surgical operation or endoscopy or from a surgically placed drain; c) Organisms cultured from blood; d) Evidence of pathologic findings on radiologic examination; e) Evidence of pathologic findings on endoscopic examination (e.g., Candida esophagitis or proctitis)

INFECTION SITE: Intraabdominal, including gallbladder, bile ducts, liver (excluding viral hepatitis), spleen, pancreas, peritoneum, subphrenic or subdiaphragmatic space, or other intraabdominal tissue or area not specicied elsewhere

CODE: GI-IAB

DEFINITION: Intraabdominal infections must meet at least one of the following criteria:

- Criterion 1: Subject has organisms cultured from purulent material from intraabdominal space obtained during a surgical operation or needle aspiration.

- Criterion 2: Subject has abscess or other evidence of intraabdominal infection seen during a surgical operation or histopathologic examination.

- Criterion 3: Subject has at least two of the following signs or symptoms with no other recognized cause: fever (>38ºC), nausea, vomiting, abdominal pain, or jaundice

and at least one of the following:

- Organisms cultured from drainage from surgically placed drain (e.g., closed suction drainage system, open drain, T-tube drain)

- Organisms seen on Gram stain of drainage or tissue obtained during surgical operation or needle aspiration

- Organisms cultured from blood and radiographic evidence of infection, for example, abnormal findings on ultrasound, CT, MRI, or radiolabel scans (gallium, technetium, etc.) or on abdominal x-ray

REPORTING INSTRUCTION

- Do not report pancreatitis (an inflammatory syndrome characterized by abdominal pain, nausea, and vomiting associated with high serum levels of pancreatic enzymes) unless it is determined to be infectious in origin.

INFECTION SITE: Bronchitis, tracheobronchitis, bronchiolitis, tracheitis, without evidence of pneumonia

CODE: LRI-BRON

DEFINITION: Tracheobronchial infections must meet at least one of the following criteria:

- Criterion 1: Subject has no clinical or radiographic evidence of pneumonia

and

- Criterion 2: Subject has at least two of the following signs or symptoms with no other recognized cause: 1) fever (>38ºC); 2) cough; 3) new and increased sputum production, rhonchi, wheezing

and subject has at least one of the following: 1) positive culture obtained by deep tracheal aspirate or bronchoscopy or 2) positive antigen test on respiratory secretions.

INFECTION SITE: Other infections of the lower respiratory tract

CODE: LRI-LUNG

DEFINITION: Other infections of the lower respiratory tract must meet at least one of the following criteria:

- Criterion 1: Subject has organisms seen on smear or cultured from lung tissue or fluid, including pleural fluid.

- Criterion 2: Subject has a lung abscess or empyema seen during a surgical operation or histopathologic examination.

- Criterion 3: Subject has an abscess cavity seen on radiographic examination of lung.

REPORTING INSTRUCTIONS

- Report concurrent lower respiratory tract infection and pneumonia with the same organism(s) as PNEU.

- Report lung abscess or empyema without pneumonia as LUNG.

INFECTION SITE: Skin

CODE: SST-SKIN

DEFINITION: Skin infections must meet at least one of the following criteria:

- Criterion 1: Subject has purulent drainage, pustules, vesicles, or boils.

- Criterion 2: Subject has at least two of the following signs or symptoms with no other recognized cause: pain or tenderness, localized swelling, redness, or heat

and at least one of the following:

- Organisms cultured from aspirate or drainage from affected site; if organisms are normal skin flora (e.g., coagulase negative staphylococci, micrococci, diphtheroids) they must be a pure culture.

- Organisms cultured from blood.

- Positive antigen test performed on infected tissue or blood (e.g., herpes simplex, varicella zoster, *H. influenzae, N. meningitidis*)

- Multinucleated giant cells seen on microscopic examination of affected tissue

- Diagnostic single antibody titer (IgM) or fourfold increase in paired sera (IgG) for pathogen

COMMENT: Nosocomial skin infections may be the result of exposure to a variety of procedures performed in the hospital. Superficial incisional infections after surgery are identified separately as SSI-SKIN unless the operative procedure is a CBGB. If the chest incision site after a CBGB becomes infected, the specific site is denoted SKNC; if the donor site becomes infected, the specific site is denoted SKNL. Other skin infections associated with important exposures are identified with their own sites and are listed in the section on reporting instructions.

REPORTING INSTRUCTIONS

- Report infected decubitus ulcers as DECU.

- Report infected burns as BURN.

INFECTION SITE: Soft tissue (necrotizing fascitis, infectious gangrene, necrotizing cellulitis,infectious myositis, lymphadenitis, or lymphangitis)

CODE:SST-ST

DEFINITION:Soft tissue infections must meet at least one of the following criteria:

- Criterion 1: Subject has organisms cultured from tissue or drainage from affected site.

- Criterion 2: Subject has purulent drainage at affected site.

- Criterion 3: Subject has an abscess or other evidence of infection seen during a surgical operation or histopathologic examination.

- Criterion 4: Subject has at least two of the following signs or symptoms at the affected site with no other recognized cause: 1) localized pain or tenderness, redness, swelling, or heat

and at least one of the following:

1) Organisms cultured from blood; 2) Positive antigen test performed on blood or urine (e.g., *H. influenzae, S. pneumoniae, N. meningitidis*, group B *Streptococcus, Candida* sp.); 3) Diagnostic single antibody titer (IgM) or fourfold increase in paired sera (IgG) for pathogen

REPORTING INSTRUCTIONS

- Report surgical site infections that involve both the skin and deep soft tissue (at or beneath the fascial or muscle layer) as SSI-ST (soft tissue) unless the operative procedure is a CBGB. For CBGB, if skin and deep

soft tissue at the chest incision site become infected, the specific site is STC and if skin and deep soft tissue at the donor site become infected, the specific site is STL.

- Report infected decubitus ulcers as DECU.

- Report infection of deep pelvic tissues as OREP.

INFECTION SITE: Decubitus ulcer, including both superficial and deep infections

CODE: SST-DECU

DEFINITION: Decubitus ulcer infections must meet the following criterion:

- Subject has at least two of the following signs or symptoms with no other recognized cause: redness, tenderness, or swelling of decubitus wound edges

and at least one of the following:

- Organisms cultured from properly collected fluid or tissue

- Organisms cultured from blood

COMMENTS:

- Purulent drainage alone is not sufficient evidence of an infection.

- Organisms cultured from the surface of a decubitus ulcer are not sufficient evidence that the ulcer is infected. A properly collected specimen from a decubitus ulcer involves needle aspiration of fluid or biopsy of tissue from the ulcer margin.

GLND **SUSPECTED NOSOCOMIAL INFECTIONS LOG** **Page 1 of** ☐☐

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (F M L) Form Completed By (Initials): ☐☐☐ (F M L)

All suspected nosocomial infections should be recorded, beginning with existing suspected infections at patient randomization.

Complete a Suspected Nosocomial Infection Form for each determined nosocomial infection, or suspected but undetermined nosocomial infection.

REFER TO APPENDIX 7 OF THE STUDY MANUAL OF OPERATIONS FOR INFECTION DIAGNOSIS PROCEDURES, DEFINITIONS AND CODES

Infection Number	Onset Date (mm/dd/yy)	Maximum Body Temp. (^{o}C)	Details	Nosocomial infection?	Infection Site & Type Code (from CRF Sect. 3)
1.	___/___/___	___ . __	_____	__ Yes __ Undetermined __ No	_____ – _____
2.	___/___/___	___ . __	_____	__ Yes __ Undetermined __ No	_____ – _____
3.	___/___/___	___ . __	_____	__ Yes __ Undetermined __ No	_____ – _____
4.	___/___/___	___ . __	_____	__ Yes __ Undetermined __ No	_____ – _____
5.	___/___/___	___ . __	_____	__ Yes __ Undetermined __ No	_____ – _____
6.	___/___/___	___ . __	_____	__ Yes __ Undetermined __ No	_____ – _____
7.	___/___/___	___ . __	_____	__ Yes __ Undetermined __ No	_____ – _____
8.	___/___/___	___ . __	_____	__ Yes __ Undetermined __ No	_____ – _____
9.	___/___/___	___ . __	_____	__ Yes __ Undetermined __ No	_____ – _____
10.	___/___/___	___ . __	_____	__ Yes __ Undetermined __ No	_____ – _____

Comments: _____

GLND **SUSPECTED NOSOCOMIAL INFECTIONS LOG** **Page 2 of** ☐☐

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ (F M L) Form Completed By (Initials): ☐☐☐ (F M L)

All suspected nosocomial infections should be recorded, beginning with existing suspected infections at patient randomization.

Complete a Suspected Nosocomial Infection Form for each determined nosocomial infection, or suspected but undetermined nosocomial infection.

REFER TO APPENDIX 7 OF THE STUDY MANUAL OF OPERATIONS FOR INFECTION DIAGNOSIS PROCEDURES, DEFINITIONS AND CODES

Infection Number	Onset Date (mm/dd/yy)	Maximum Body Temp. (^{o}C)	Details	Nosocomial infection?	Infection Site & Type Code (from CRF Sect. 3)
11.	___/___/___	___ . __	_____	__ Yes __ Undetermined __ No	_____ – _____
12.	___/___/___	___ . __	_____	__ Yes __ Undetermined __ No	_____ – _____
13.	___/___/___	___ . __	_____	__ Yes __ Undetermined __ No	_____ – _____
14.	___/___/___	___ . __	_____	__ Yes __ Undetermined __ No	_____ – _____
15.	___/___/___	___ . __	_____	__ Yes __ Undetermined __ No	_____ – _____
16.	___/___/___	___ . __	_____	__ Yes __ Undetermined __ No	_____ – _____
17.	___/___/___	___ . __	_____	__ Yes __ Undetermined __ No	_____ – _____
18.	___/___/___	___ . __	_____	__ Yes __ Undetermined __ No	_____ – _____
19.	___/___/___	___ . __	_____	__ Yes __ Undetermined __ No	_____ – _____
20.	___/___/___	___ . __	_____	__ Yes __ Undetermined __ No	_____ – _____

Comments: _____

GLND **SUSPECTED NOSOCOMIAL INFECTIONS LOG** **Page 3 of** ☐☐

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21.	___/___/___	___ . __	_____	__ Yes __ Undetermined __ No	_____ – _____
22.	___/___/___	___ . __	_____	__ Yes __ Undetermined __ No	_____ – _____
23.	___/___/___	___ . __	_____	__ Yes __ Undetermined __ No	_____ – _____
24.	___/___/___	___ . __	_____	__ Yes __ Undetermined __ No	_____ – _____
25.	___/___/___	___ . __	_____	__ Yes __ Undetermined __ No	_____ – _____
26.	___/___/___	___ . __	_____	__ Yes __ Undetermined __ No	_____ – _____
27.	___/___/___	___ . __	_____	__ Yes __ Undetermined __ No	_____ – _____
28.	___/___/___	___ . __	_____	__ Yes __ Undetermined __ No	_____ – _____
29.	___/___/___	___ . __	_____	__ Yes __ Undetermined __ No	_____ – _____
30.	___/___/___	___ . __	_____	__ Yes __ Undetermined __ No	_____ – _____

Comments: _____

ADVERSE EVENTS LOG

TAB PAGE

GLND **ADVERSE EVENTS LOG** **Page 1 of** ☐☐

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ *(F-M-L)* Form Completed By (Initials): ☐☐☐ *(F-M-L)*

Serious Adverse Event Codes

01 Death
02 Anaphylactic reaction
03 Seizure
04 Cardiopulmonary arrest
05 Re-hospitalization*
06 Re-operation*
** Within 30 days of study drug discontinuation*
07 New cancer diagnosis
08 Congenital anamoly / disorder

Adverse Event Codes

11 Respiratory distress / failure
12 Tracheostomy
13 Pulmonary aspiration
14 Pneumothorax
15 Pulmonary emboli
16 Wound dehiscence
17 New onset significant hemorrhage
18 Mechanical intestinal obstruction
19 Worse renal function (creatinine ≥ 5.0 mg/dL)
20 Worse hepatic function (billirubin ≥ 15.0 mg/dL)
21 Myocardial infarction
22 Cerebrovascular accident
23 ICU / SICU re-admission
24 New onset skin rash
25 Hyperglycemia > 250 mg/dL
26 Non-infectious pancreatitis
27 Encephalopathy

AE No.	Onset Date (mm/dd/yy)	AE Description	SAE or AE Code	Mark When Resolved	Date Resolved (mm/dd/yy)
1.	___/___/___	_____	_____ (If 01-08, expedite reporting)	☐	___/___/___
2.	___/___/___	_____	_____ (If 01-08, expedite reporting)	☐	___/___/___
3.	___/___/___	_____	_____ (If 01-08, expedite reporting)	☐	___/___/___
4.	___/___/___	_____	_____ (If 01-08, expedite reporting)	☐	___/___/___
5.	___/___/___	_____	_____ (If 01-08, expedite reporting)	☐	___/___/___
6.	___/___/___	_____	_____ (If 01-08, expedite reporting)	☐	___/___/___
7.	___/___/___	_____	_____ (If 01-08, expedite reporting)	☐	___/___/___
8.	___/___/___	_____	_____ (If 01-08, expedite reporting)	☐	___/___/___
9.	___/___/___	_____	_____ (If 01-08, expedite reporting)	☐	___/___/___
10.	___/___/___	_____	_____ (If 01-08, expedite reporting)	☐	___/___/___

Comments: _____

GLND **ADVERSE EVENTS LOG** **Page 2 of** ☐☐

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ *(F-M-L)* Form Completed By (Initials): ☐☐☐ *(F-M-L)*

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12.	___/___/___	_____	_____ (If 01-08, expedite reporting)	☐	___/___/___
13.	___/___/___	_____	_____ (If 01-08, expedite reporting)	☐	___/___/___
14.	___/___/___	_____	_____ (If 01-08, expedite reporting)	☐	___/___/___
15.	___/___/___	_____	_____ (If 01-08, expedite reporting)	☐	___/___/___
16.	___/___/___	_____	_____ (If 01-08, expedite reporting)	☐	___/___/___
17.	___/___/___	_____	_____ (If 01-08, expedite reporting)	☐	___/___/___
18.	___/___/___	_____	_____ (If 01-08, expedite reporting)	☐	___/___/___
19.	___/___/___	_____	_____ (If 01-08, expedite reporting)	☐	___/___/___
20.	___/___/___	_____	_____ (If 01-08, expedite reporting)	☐	___/___/___

Comments: _____

GLND **ADVERSE EVENTS LOG** **Page 3 of** ☐☐

GLND ID No.: ☐ - ☐☐☐☐ Participant Initials: ☐☐☐ *(F-M-L)* Form Completed By (Initials): ☐☐☐ *(F-M-L)*

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21.	___/___/___	_____	_____ (If 01-08, expedite reporting)	☐	___/___/___
22.	___/___/___	_____	_____ (If 01-08, expedite reporting)	☐	___/___/___
23.	___/___/___	_____	_____ (If 01-08, expedite reporting)	☐	___/___/___
24.	___/___/___	_____	_____ (If 01-08, expedite reporting)	☐	___/___/___
25.	___/___/___	_____	_____ (If 01-08, expedite reporting)	☐	___/___/___
26.	___/___/___	_____	_____ (If 01-08, expedite reporting)	☐	___/___/___
27.	___/___/___	_____	_____ (If 01-08, expedite reporting)	☐	___/___/___
28.	___/___/___	_____	_____ (If 01-08, expedite reporting)	☐	___/___/___
29.	___/___/___	_____	_____ (If 01-08, expedite reporting)	☐	___/___/___
30.	___/___/___	_____	_____ (If 01-08, expedite reporting)	☐	___/___/___

Comments: _____