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General Instructions

Note: Please see also the instructions at the CRF

1. Use only black ball-point ink when completing forms.
2. All data requested in the CRFs is to be taken from the patient's hospital chart. Except for follow-up and the corresponding surveys that are completed over the phone.
3. Where data is expected there can be no blanks. If no data is available standard annotations should be documented.
 - ND- not done (data is unavailable because the measure wasn't taken or test not done)
 - N/A- not applicable (measure was not required at the particular time point the form relates to)
 - N/K—not known (every effort has been made to find the data)
4. To perform a corrections made in the CRF never use correction fluid. Corrections should be made by crossing the initial entry out by a single line, ensuring the original data is legible. The correct entry should be placed beside this and confirmed with date, initialing the correction. e.g: 106
5. Standard date will be entered as dd/mmm/yyyy.
6. The study clock is the 24-hr clock. Midnight is 00:00 and the date of the new day.
7. Anywhere in the CRF that 'Other, specify' is indicated, and has been checked, there must be an entry on the line provided.



Instructions - Screening



Screening

Date and time of screening

 :

(24 hour clock)

Inclusion Criteria

Reason 1

 Yes No

Reason 2

 Yes No

Reason 3

 Yes No

Reason 4

 Yes No

Reason 5

 Yes No

Reason 6

 Yes No

Exclusion Criteria

Reason 1

 Yes No

Reason 2

 Yes No

Reason 3

 Yes No

Reason 4

 Yes No

Reason 5

 Yes No

Reason 6

 Yes No



Instructions - Randomization



Randomization

Patient eligibility confirmed?

Yes No

Was consent obtained? If no, go to reasons not consented/randomized

Yes No

Date and time of consent

D	D	M	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---

H	H	:	M	M
---	---	---	---	---

(24 hour clock)

Date and time of randomization

D	D	M	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---

H	H	:	M	M
---	---	---	---	---

(24 hour clock)

Reason patient not consented/randomized?

- No family present
- Refused consent
- Missed the patient
- Other specify _____



Instructions - APACHE II



				-				
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Site Number

Enrolment #

<Name of Study / Study # / Logo>



Instructions - Baseline

Sex

Place a √ in the appropriate box (male or female) will be expected. Tick only one box.

Weight

Record weight. Place a √ in the appropriate measurement scale (pounds or kilograms)

Ethnicity

Place a √ in the appropriate box. Tick only one box.

- If ethnicity is 'other', a specification will be expected on the line provided.

Diabetic

Indicate with a √ in the appropriate box.

- If 'Yes' Indicate with a √ either for Type I (juvenile diabetic or insulin dependent) or for Type 2 (non-insulin dependent diabetes, adult onset or insulin resistant diabetes)

Type of Admission

Indicate the type of admission to ICU. Place a √ in the appropriate box.

Primary ICU Diagnosis

Choose the most pertinent diagnosis that resulted in the patient's admission to ICU.

From the type of ICU admission choose the corresponding admission diagnosis from the taxonomy

Comorbidities

Enter all that apply from the taxonomy provided. If the comorbidity doesn't appear in the taxonomy then do not document it.

Hospital admission/Emergency Presentation date and time

A complete date and time will be expected.

For the patient that is admitted to hospital through emergency this is the same as the date and time of admission to emergency.

For the patient that is admitted to the hospital directly, this is the same as the date and time of admission to hospital.

ICU admission data and time

A complete date and time will be expected.

Enter the date and time admitted to your ICU.

This date cannot be before hospital admission/emergency presentation date and time

Mechanical ventilation start date and time

A complete date and time will be expected.

Enter the date and time of invasive mechanical ventilation.

For the patient that is mechanically ventilated prior to admission to your hospital this is the same as the admission date and time to your hospital.



Instructions - Baseline Nutrition



Baseline Nutrition

Prescribed energy intake

kilojoules

kilocalories

Prescribed protein intake

grams

Enteral Nutrition

Never received in ICU

Enteral nutrition initiated prior to ICU admission & continued in ICU

Date and time enteral nutrition stopped

D	D	M	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---

H	H	:	M	M
---	---	---	---	---

(24 hour clock)

Enteral nutrition initiated in ICU admission & continued in ICU

Date and time enteral nutrition started

D	D	M	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---

H	H	:	M	M
---	---	---	---	---

(24 hour clock)

Date and time enteral nutrition stopped

D	D	M	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---

H	H	:	M	M
---	---	---	---	---

(24 hour clock)

Parenteral Nutrition

Never received in ICU

Parenteral nutrition initiated prior to ICU admission & continued in ICU

Date and time parenteral nutrition stopped

D	D	M	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---

H	H	:	M	M
---	---	---	---	---

(24 hour clock)

Parenteral nutrition initiated in ICU admission & continued in ICU

Date and time parenteral nutrition started

D	D	M	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---

H	H	:	M	M
---	---	---	---	---

(24 hour clock)

Date and time parenteral nutrition stopped

D	D	M	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---

H	H	:	M	M
---	---	---	---	---

(24 hour clock)



Instructions - Microbiology



<Name of Study / Study # / Logo>

Microbiology Page __ of __

Complete 1 box per positive sample

Sample type <input type="checkbox"/> Blood <input type="checkbox"/> Endotracheal aspiration <input type="checkbox"/> BAL or PBC* <input type="checkbox"/> Wound <input type="checkbox"/> Cath tip/line <input type="checkbox"/> Urine* <input type="checkbox"/> Stool <input type="checkbox"/> Other	Accession Number _____ Date and Time of Culture: <table border="1" style="display: inline-table; margin: 0 5px;"> <tr><td>D</td><td>D</td></tr> </table> <table border="1" style="display: inline-table; margin: 0 5px;"> <tr><td>M</td><td>M</td><td>M</td></tr> </table> <table border="1" style="display: inline-table; margin: 0 5px;"> <tr><td>Y</td><td>Y</td><td>Y</td><td>Y</td></tr> </table> <table border="1" style="display: inline-table; margin: 0 5px;"> <tr><td>H</td><td>H</td></tr> </table> <table border="1" style="display: inline-table; margin: 0 5px;"> <tr><td>M</td><td>M</td></tr> </table> (24 hour clock)	D	D	M	M	M	Y	Y	Y	Y	H	H	M	M
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	M	M	M											
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M	M													
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Organism 1	Susceptibilities 1													
Organism 2	Susceptibilities 2													
Organism 3	Susceptibilities 3													
Quantitative Results* $>10^4$ cfu/ml or $>10^7$ cfu/L <input type="checkbox"/> $<10^4$ cfu/ml or $<10^7$ cfu/L <input type="checkbox"/> None <input type="checkbox"/>														

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	M	M	M											
	Y	Y	Y	Y										
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Instructions - Antibiotic



Instructions - Outcomes



<Name of Study / Study # / Logo>

Outcomes

Mechanical ventilation discontinuation:

D	D	M	M	M	Y	Y	Y	Y	H	H	:	M	M
---	---	---	---	---	---	---	---	---	---	---	---	---	---

(24 hour clock)

Termination date of dialysis

D	D	M	M	M	Y	Y	Y	Y	H	H	:	M	M
---	---	---	---	---	---	---	---	---	---	---	---	---	---

(24 hour clock)

ICU discharge:

D	D	M	M	M	Y	Y	Y	Y	H	H	:	M	M
---	---	---	---	---	---	---	---	---	---	---	---	---	---

(24 hour clock)

Hospital discharge:

D	D	M	M	M	Y	Y	Y	Y	H	H	:	M	M
---	---	---	---	---	---	---	---	---	---	---	---	---	---

(24 hour clock)

Death:

D	D	M	M	M	Y	Y	Y	Y	H	H	:	M	M
---	---	---	---	---	---	---	---	---	---	---	---	---	---

(24 hour clock)

N/A



Instructions - Follow-Up



Follow up

3 Month

6 Month

Were you able to conduct the follow up survey?

Yes

Date of interview

D	D	M	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---

Interview completed by

Patient

Family/Caregiver

No, patient died

Date of death

Unknown

D	D	M	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---

No, patient refused

Date of refusal

D	D	M	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---

No, patient lost to follow up

Date of last known to be alive

D	D	M	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---

No, missed timeline requirement



Instructions - Comments



Comments

Comment Date	Form/ Study Day #	Comment details
<input type="text" value="D"/> <input type="text" value="D"/> <input type="text" value="M"/> <input type="text" value="M"/> <input type="text" value="M"/> <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/> <input type="text" value="Y"/>		
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Instructions - Investigator Confirmation



<Name of Study / Study # / Logo>

Investigator Confirmation

The treatment of this patient was conducted under my supervision according to the protocol during the entire study period. The statements and data contained in this case report form are complete and accurate to the best of my knowledge.

D	D	M	M	M	Y	Y	Y	Y
---	---	---	---	---	---	---	---	---

Full signature of investigator