



1. Purpose

The objective of this standard operating procedure is to outline how to design protocol specific paper Case Report Forms (CRFs).

2. Responsibilities

Sponsor/Principal Investigator: Develop protocol and establish the required data elements and analysis plan.

Delegated Methods Centre Staff: Develop the data dictionary and specifications document for development of a paper based case report form.

3. Procedures

- 3.1 CRFs are the instruments used to record participant data for a research study.
- 3.2 All CRFs should collect trial data, in an appropriate format, as set out in the protocol.
- 3.3 Data collection in excess of what is required by the protocol and data analysis plan is undesirable.
- 3.4 Standard CRFs usually include, but are not limited to, the following modules/forms:
 - 3.4.1 Inclusion/Exclusion
 - 3.4.2 APACHE II
 - 3.4.3 Randomization
 - 3.4.4 Baseline demographics
 - 3.4.5 Treatment/Intervention/Device forms
 - 3.4.6 Vasopressors
 - 3.4.7 Concomitant Medications
 - 3.4.8 Microbiology
 - 3.4.9 Antibiotic
 - 3.4.10 Outcomes
 - 3.4.11 Adverse Events
 - 3.4.12 Serious Adverse Events (see SOP #302)
 - 3.4.13 Comments
 - 3.4.14 Follow-up
 - 3.4.15 Investigator Signature Form
 - 3.4.16 Taxonomies
- 3.5 CRF development should commence once study funds have been awarded for a particular protocol or once requested by the PI.
- 3.6 Using the study protocol, the Sponsor/Principal Investigator, or delegate, will establish the data elements required to answer the study primary and secondary questions. This will be done in conjunction with the analysis plan to ensure the collected data will adequately answer the primary & secondary questions. (See SOP #xx)



Paper Based CRFs

- 3.7 For studies using a paper CRF, the delegated MC staff, in consultation with the Sponsor/Principal Investigator, will develop the specifications document, sometimes referred to as data dictionary (see Appendix 1 for an example).
- 3.8 The specifications documented will include the information required for construction of the database, in addition to details required for the development of paper CRFs.
- 3.9 MC staff will draft paper CRFs. The sequence of forms usually mirrors the patient's hospital stay (i.e. admission, daily monitoring, and discharge).
- 3.10 The draft CRFs will be forwarded to PL; DM; POG group, site coordinators and then the PI for feedback concerning format, data fields, logic etc. This process will continue until the paper CRF is finalized.
- 3.11 During the development phase, each version of the CRF is to be identified by a version number and/or date. Any changes to the finalized version of the CRF used during a trial should be documented.
- 3.12 MC personnel will verify that the CRF includes the established data elements and by comparing with the study protocol.
- 3.13 The final CRF product which is to be circulated to participating sites should include:
- 3.13.1 General instructions:
 - 3.13.1.1 To use black ink when completing forms.
 - 3.13.1.2 Complete all fields.
 - 3.13.1.3 Instructions, including taxonomies and algorithms, are included.
 - 3.13.1.4 Contact information
 - 3.13.1.5 Procedures for corrections
 - 3.13.1.6 CRF completion schedule

 - 3.13.2 Design Guide:
 - 3.13.2.1 For ease of completion:
 - 3.13.2.1.1 Provide definitions
 - 3.13.2.1.2 Specify units if appropriate. Consider US & Canadian both
 - 3.13.2.1.3 Collect raw data rather than calculated data (e.g. collect height & weight to calculate BMI rather than asking for BMI)

 - 3.13.2.2 For ease of understanding:
 - 3.13.2.2.1 Avoid double negatives
 - 3.13.2.2.2 Ask explicit questions
 - 3.13.2.2.3 Use absolute questions
 - 3.13.2.2.4 Avoid compound questions



3.13.3 Layout:

- 3.13.3.1 Ensure margins, alignment; fonts are consistent throughout CRF package.
- 3.13.3.2 Align tick boxes to left or centered so it is understood which tick box corresponds to which question.
- 3.13.3.4 Group same type of data together on the same form
- 3.13.3.5 On each CRF the header should include:
 - 3.13.3.5.1 Name of study or study number and/or logo
 - 3.13.3.5.2 Site number
 - 3.13.3.5.3 Enrolment number
 - 3.13.3.5.4 Title of form
 - 3.13.3.5.5 Number of form
 - 3.13.3.5.6 Indicate extra pages for same CRF as Form Number of form followed by .1, .2, .3
i.e 3 Daily Data for extra pages 3.1; 3.2; 3.3

<p><Study Logo/Name of Study></p> <p>< Form number> <Name of form></p>	<table style="margin: auto;"><tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="width: 10px; text-align: center;">-</td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr><tr><td colspan="4">Site number</td><td></td><td colspan="4">Enrolment number</td></tr></table>					-				Site number					Enrolment number			
				-														
Site number					Enrolment number													

- 3.13.3.6 The footer should contain the final version date and revision date should be included at the bottom of the page along with the page number for that CRF.


<p>Final version date: _____</p> <p>Revision date: _____</p>	<p>Page # ____</p>
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3.13.4. Types of data collection responses:

- 3.13.4.1 Open text, number or alpha numeric (e.g. dates, age)
Avoid free text as it is impossible to analyze. For date and time fields add characters to ensure dates are collected in a uniform fashion. (dd/mmm/yyyy).
- 3.13.4.2 Closed Check box, multiple choice
Provides a list of options i.e. yes/no. Checkboxes are the clearest option.
- 3.13.4.3 Combination Open and closed
Used mostly with closed type questions when you have a response option of "Other or Specify".
- 3.13.4.4 Analogue/rating scales
Use validated tools e.g SF-36



3.14 Boxes should be consistent design through the CRFs. Types to use are:

3.14.1 Box dividing 

3.14.2 Box combing 

3.14.3 Free text _____

3.14.4 Tick boxes tend to be the easiest to complete and utilize for data entry. Use a standardized answer mode throughout all CRFs like tick boxes.

Sex Male Female

3.15 Completing CRFs

3.15.1 Fields should never be left blank. Use standard annotations for:

Not done (**ND**) – used if data is unavailable either because a measure wasn't taken or test not done

Not applicable (**N/A**) – should be used if measure was not required at the particular time point the form relates to

Unknown (**NK**) – used if data is unknown and every effort has been made to find the data.

3.15.2 Completed CRFs should be signed-off by the qualified investigator at the site, or delegate.

3.16 Corrections to CRF Entries

3.16.1 As a rule, corrections to the data recorded on CRFs should always be handled at the local site. Corrections should be made by drawing a single line through the incorrect item, entering the correct data and dating and initialing the correction.

3.16.2 When completing a query, attach an amended copy of the CRF and return as per study specific instructions.

3.16.3 The final version of the paper based CRFs will be made available to sites in a read-only format (PDF).

3.16.4 Any changes to a finalized CRF should be documented (including rationale for changes, additions and deletions) and dated.

4. Appendices

4.1 Appendix 1 Sample Data Element Table



Case Report Form Development
405-00
4.2 Appendix 2 CRFs

5. References

Prokscha, S. (2007). CRF Design Considerations. In: Practical Guide to Clinical Data Management. FL: Taylor & Francis Group. 9-18.

Patient Characteristics- baseline measurements for each included patient (one time only)

Data Element	response options	comments
age	date of birth	
admission diagnosis	numerical (range 1-100?)	Use taxonomy
surgical status	categorical: 1=elective surgical 2=emergency surgery 3=medical	
ICU Admission Date and Time	date and time	
Admission APACHE II scores	numerical (range 1-50)	use APACHE II worksheet
sex	1=female, 2= male	
date and time EN initiated	date and time, never	
date and time PN initiated	date and time, never	
At Initial assessment, total prescribed amount of protein	numerical (range 1-150 gms/day)	should this be on daily data collection?
At initial assessment, total prescribed amount of energy (non-protein)	numerical (range 1-1200 kjoules)	ditto
Formula type	Numerical (from taxonomy)	need to develop a taxonomy of common products



Table of Contents

General Instructions	
Screening	
APACHE II	
Randomization	
Baseline	
Baseline Nutrition	
Daily Data	
Daily Laboratory Measurements	
Daily Enteral Nutrition	
Daily Parenteral Nutrition	
Concomitant Medications	
Vasopressors	
Microbiology	
Antibiotics	
Outcomes	
Follow Up	
Comments	
Investigator Confirmation	
Appendices—taxonomies	



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

APACHE II Worksheet

Physiological Variables

Enter the highest and lowest values for all variables within the first 24 hours from admission to ICU.

	LOW	High	
Temperature (C)	<input type="text"/>	<input type="text"/>	Route <input type="text"/>
Systolic BP (mmHg)	<input type="text"/>	<input type="text"/>	
Diastolic BP (mmHg)	<input type="text"/>	<input type="text"/>	
Heart Rate	<input type="text"/>	<input type="text"/>	
Respiratory Rate	<input type="text"/>	<input type="text"/>	
Arterial pH	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> NO ABGs If no ABGs, enter serum HCO₃ (venous mmol/L)
FiO ₂	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> NO ABGs
PaO ₂	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> NO ABGs LOW <input type="text"/>
PaCO ₂ (not required if FiO ₂ < 0.5)	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> NO ABGs HIGH <input type="text"/>
Serum Sodium (mmol/)	<input type="text"/>	<input type="text"/>	
Serum Potassium (mmol/)	<input type="text"/>	<input type="text"/>	
Serum Creatinine (mmol/)	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> Acute Renal Failure
Hematocrit (%)	<input type="text"/>	<input type="text"/>	
WBC (total/mm ³)	<input type="text"/>	<input type="text"/>	

GCS choose the best score

Eye Opening	<input type="text"/>
Verbal Response	<input type="text"/>
Best Motor Response	<input type="text"/>

If the patient is sedated, then go back to the period of time when the patient was not receiving sedation or approximate what the score would be if the sedation were to be removed.

Chronic Health Points

- No history of severe organ system insufficiency AND not immunocompromised
- Elective post-operative patient
- Non-operative OR emergency post-operative patient

Choose one of the 3 categories to assign chronic health points.
NOTE: Organ insufficiency or immunocompromised state evident prior to this hospital admission.

SEVERITY SCORES AND TOTAL APACHE II SCORE WILL BE CALCULATED BY THE METHODS CENTRE .



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 - Daily Data



<Name of Study / Study # / Logo>

Daily Data Page __ of __

	ICU Admit	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10
DATE dd/mmm/yyyy										
Heart Rate Highest										
Blood Pressure Lowest										
Temperature Core										
Urine Output	<input type="checkbox"/> 0-199 mls <input type="checkbox"/> 200-499 mls <input type="checkbox"/> ≥ 500 mls	<input type="checkbox"/> 0-199 mls <input type="checkbox"/> 200-499 mls <input type="checkbox"/> ≥ 500 mls	<input type="checkbox"/> 0-199 mls <input type="checkbox"/> 200-499 mls <input type="checkbox"/> ≥ 500 mls	<input type="checkbox"/> 0-199 mls <input type="checkbox"/> 200-499 mls <input type="checkbox"/> ≥ 500 mls	<input type="checkbox"/> 0-199 mls <input type="checkbox"/> 200-499 mls <input type="checkbox"/> ≥ 500 mls	<input type="checkbox"/> 0-199 mls <input type="checkbox"/> 200-499 mls <input type="checkbox"/> ≥ 500 mls	<input type="checkbox"/> 0-199 mls <input type="checkbox"/> 200-499 mls <input type="checkbox"/> ≥ 500 mls	<input type="checkbox"/> 0-199 mls <input type="checkbox"/> 200-499 mls <input type="checkbox"/> ≥ 500 mls	<input type="checkbox"/> 0-199 mls <input type="checkbox"/> 200-499 mls <input type="checkbox"/> ≥ 500 mls	<input type="checkbox"/> 0-199 mls <input type="checkbox"/> 200-499 mls <input type="checkbox"/> ≥ 500 mls
Diarrhea > 750 mls or > 5/day	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Gastric Residual Volume										
Gastric Residual Volume Discarded										
Dialysis	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
If Yes because of Acute Renal Failure	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Location of feeding tube										



<Name of Study / Study # / Logo>

Instructions - Daily Laboratory Measurements



<Name of Study / Study # / Logo>

Daily Laboratory Measurements Page __ of __

	ICU admit	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10
DATE dd/mmm/yyyy										
WBC High										
WBC Low										
Platelets Low										
Blood Sugar (BS) am										
Serum Creatinine high										
Serum Urea High										
Serum Albumin high										
Serum Bilirubin high										



Instructions - Daily Enteral Nutrition



Daily Enteral Nutrition Page __ of __

	ICU Admit	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10
DATE dd/mmm/yyyy										
Enteral Nutrition received today?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Formula Collect up to 3	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>
Formulation Cals/ml Protein per ml	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Volume (mls) received in 24 hrs for each formula										
Did the patient receive propofol today?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Volume (mls) received in 24 hrs										



Instructions—Daily Parenteral Nutrition



Daily Parenteral Nutrition Page __ of __

	ICU Admit	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10
DATE dd/mmm/yyyy										
Parenteral Nutrition received today?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Mls of Amino Acids Kcals/ml Protein/ml										
Volume received in 24 hrs										
Lipids received?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Type of Lipids										
Volume of lipids received										



Instructions—Concomitant Medication



Concomitant Medication Page __ of __

	ICU Admit	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10
DATE dd/mmm/yyyy										
Receive any today?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Hydrocortisone	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Activated Protein C	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Motility agents	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes which ones	<input type="checkbox"/> Metoclopramide <input type="checkbox"/> Motilium <input type="checkbox"/> Erythromycin	<input type="checkbox"/> Metoclopra- <input type="checkbox"/> Motilium <input type="checkbox"/> Erythromycin	<input type="checkbox"/> Metoclopramide <input type="checkbox"/> Motilium <input type="checkbox"/> Erythromycin	<input type="checkbox"/> Metoclopramide <input type="checkbox"/> Motilium <input type="checkbox"/> Erythromycin	<input type="checkbox"/> Metoclopra- <input type="checkbox"/> Motilium <input type="checkbox"/> Erythromycin	<input type="checkbox"/> Metoclopramide <input type="checkbox"/> Motilium <input type="checkbox"/> Erythromycin	<input type="checkbox"/> Metoclopramide <input type="checkbox"/> Motilium <input type="checkbox"/> Erythromycin	<input type="checkbox"/> Metoclopramide <input type="checkbox"/> Motilium <input type="checkbox"/> Erythromycin	<input type="checkbox"/> Metoclopramide <input type="checkbox"/> Motilium <input type="checkbox"/> Erythromycin	<input type="checkbox"/> Metoclopramide <input type="checkbox"/> Motilium <input type="checkbox"/> Erythromycin
Insulin Total <input type="checkbox"/> units/day										



Instructions - Vasopressor



<Name of Study / Study # / Logo>

Vasopressor Page __ of __

	ICU Admit	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10
DATE dd/mmm/yyyy										
Received any today?	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
Dopamine <input type="checkbox"/> ug/kg/min <input type="checkbox"/> ug/min										
Norepineph- rine <input type="checkbox"/> ug/kg/min <input type="checkbox"/> ug/min										
Epinephrine <input type="checkbox"/> ug/kg/min <input type="checkbox"/> ug/min										
Dobutamine <input type="checkbox"/> ug/kg/min <input type="checkbox"/> ug/min										
Phenylephrine <input type="checkbox"/> ug/kg/min <input type="checkbox"/> ug/min										
Milrinone <input type="checkbox"/> ug/kg/min <input type="checkbox"/> ug/min										
Vasopressin <input type="checkbox"/> units/min										



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
	D	D												
	M	M	M											
	Y	Y	Y	Y										
H	H													
M	M													
<table border="1" style="width: 100%;"> <tr> <td style="width: 50%;">Organism 1</td> <td>Susceptibilities 1</td> </tr> </table>	Organism 1	Susceptibilities 1												
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<table border="1" style="width: 100%;"> <tr> <td style="width: 50%;">Organism 2</td> <td>Susceptibilities 2</td> </tr> </table>	Organism 2	Susceptibilities 2												
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<table border="1" style="width: 100%;"> <tr> <td style="width: 50%;">Organism 3</td> <td>Susceptibilities 3</td> </tr> </table>	Organism 3	Susceptibilities 3												
Organism 3	Susceptibilities 3													

Quantitative Results*

>10⁴ cfu/ml or >10⁷ cfu/L <10⁴ cfu/ml or <10⁷ cfu/L None

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
	D	D												
	M	M	M											
	Y	Y	Y	Y										
H	H													
M	M													
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Organism 3	Susceptibilities 3													

Quantitative Results*

>10⁴ cfu/ml or >10⁷ cfu/L <10⁴ cfu/ml or <10⁷ cfu/L None



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



<Name of Study / Study # / Logo>

Comments

Comment Date	Form/ Study Day #	Comment details
D D M M M Y Y Y Y		
D D M M M Y Y Y Y		
D D M M M Y Y Y Y		
D D M M M Y Y Y Y		
D D M M M Y Y Y Y		
D D M M M Y Y Y Y		
D D M M M Y Y Y Y		
D D M M M Y Y Y Y		
D D M M M Y Y Y Y		
D D M M M Y Y Y Y		



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

ICU Admission Diagnosis Taxonomy

NON-OPERATIVE CONDITIONS

Choose from this list if admission category is medical

Cardiovascular / vascular:

1. Cardiogenic shock
2. Cardiac arrest
3. Aortic aneurysm
4. Congestive heart failure
5. Peripheral vascular disease
6. Rhythm disturbance
7. Acute myocardial infarction
8. Hypertension
9. Other CV disease: _____

Respiratory:

10. Parasitic pneumonia (ie.pneumocystis carinii)
11. Aspiration pneumonia
12. Respiratory neoplasm (inc. larynx, trachea)
13. Respiratory arrest
14. Pulmonary edema (non-cardiogenic)
15. Bacterial / Viral pneumonia
16. Chronic obstructive pulmonary disease
17. Pulmonary embolism
18. Mechanical airway obstruction
19. Asthma
20. Other respiratory disease: _____

Gastrointestinal:

21. Hepatic failure
22. GI perforation/obstruction
23. GI bleeding due to varices
24. GI inflammatory disease (ulcerative colitis, crohn's disease)
25. GI bleeding due to ulcer/laceration
26. GI bleeding due to diverticulosis
27. Pancreatitis
28. Other GI disease: _____

Neurologic:

29. Intracerebral hemorrhage
30. Subarachnoid hemorrhage
31. Stroke
32. Neurologic infection
33. Neurologic neoplasm
34. Neuromuscular disease
35. Seizure
36. Other neurologic disease: _____

Sepsis:

37. Sepsis (other than urinary tract)
38. Sepsis of urinary tract origin

Trauma:

39. Head trauma (with/without multiple trauma)
40. Multiple trauma (excluding head trauma)

Metabolic:

41. Metabolic coma
42. Diabetic ketoacidosis
43. Drug overdose
44. Other metabolic disease: _____

Hematologic:

45. Coagulopathy //neutropeniathrombocytopenia
46. Other hematologic condition: _____

Other:

47. Renal disease: _____

48. Burns
49. Other medical disease: _____

POST-OPERATIVE CONDITIONS:

Choose from this list if admission category is surgical

Vascular / cardiovascular:

50. Dissecting/ruptured aorta
51. Peripheral vascular surgery (no bypass graft)
52. Valvular heart surgery/CABG
53. Elective abdominal aneurysm repair
54. Peripheral artery bypass graft
55. Carotid endarterectomy
56. Other CV disease: _____

Respiratory:

57. Respiratory infection
58. Lung neoplasm
59. Respiratory neoplasm (mouth, sinus, larynx, trachea)
60. Other respiratory disease: _____

Gastrointestinal:

61. GI perforation/rupture
62. GI inflammatory disease
63. GI obstruction
64. GI bleeding
65. Pancreatitis
66. Liver transplant
67. GI neoplasm
68. GI cholecystitis / cholangitis
69. Other GI disease: _____

Neurologic:

70. Intracerebral hemorrhage
71. Subdural/epidural hematoma
72. Subarachnoid hemorrhage
73. Laminectomy/other spinal cord surgery
74. Craniotomy for neoplasm
75. Other neurologic disease: _____

Trauma:

76. Head trauma (with/without multiple trauma)
77. Multiple trauma (excluding head trauma)

Renal:

78. Renal neoplasm
79. Other renal disease: _____

Gynecologic:

80. Hysterectomy

Orthopedic:

81. Hip or extremity fracture

Bariatric Surgery:

82. Laparoscopic Banding
83. Laparoscopic Gastric Bypass
84. Open Gastric Bypass (Roux-en-Y)
85. Vertical Banded Gastroplasty

Other:

86. Other surgical condition: _____

Appendix 4 COMORBID TAXONOMY

0. NONE

MYOCARDIAL

1. Angina
2. Arrhythmia
3. Valvular
4. Myocardial infarction
5. Congestive heart failure (or heart disease)

VASCULAR

6. Hypertension
7. Peripheral vascular disease or claudication
8. Cerebrovascular disease

PULMONARY

9. Chronic obstructive pulmonary disease (COPD, emphysema)
10. Asthma

NEUROLOGIC

11. Dementia
12. Hemiplegia (paraplegia)
13. Stroke or TIA
14. Neurologic illnesses (such as Multiple sclerosis or Parkinsons)

ENDOCRINE

15. Diabetes Type I or II
16. Diabetes with end organ damage
17. Obesity and/or BMI > 30 (weight in kg/(ht in meters)²)

RENAL

18. Moderate or severe renal disease

GASTROINTESTINAL

19. Mild liver disease
20. Moderate or severe liver disease
21. GI Bleeding
22. Inflammatory bowel
23. Peptic ulcer disease
24. Gastrointestinal Disease (hernia, reflux)

CANCER/IMMUNE

25. Any Tumor
26. Lymphoma
27. Leukemia
28. AIDS
29. Metastatic solid tumor

PSYCHOLOGICAL

30. Anxiety or Panic Disorders
31. Depression

MUSKOSKELETAL

32. Arthritis (Rheumatoid or Osteoarthritis)
33. Degenerative Disc disease (back disease, spinal stenosis or severe chronic back pain)
34. Osteoporosis
35. Connective Tissue disease

MISCELLANEOUS

36. Visual Impairment (cataracts, glaucoma, macular degeneration)
37. Hearing Impairment (very hard of hearing even with hearing aids)

FORMULA TAXONOMY

Code	Formula Name	Code	Formula Name
1.	MEAD JOHNSON: Portagen	31	NOVARTIS: Vivonex TEN
2.	NESTLE: Peptamen with Prebio 1	32	NOVARTIS: Vivonex Plus
3.	NESTLE: Peptamen	33	NOVARTIS: Supplements- Instant Protein Powder
4.	NESTLE: Peptamen 1.5	34	NOVARTIS: Supplements - Microlipid
5.	NESTLE: Peptamen VHP	35	NOVARTIS: Supplements - MCT oil
6.	NESTLE: Peptamen AF	36	NOVARTIS: Supplements-Resource Glutasolve
7.	NESTLE: Nutren 2.0	37	ROSS: Jevity 1 kcal
8.	NESTLE: Nutren 1.5	38	ROSS: Jevity 1.2 kcal
9.	NESTLE: Nutren VHP	39	ROSS: Osmolite HN Plus
10.	NESTLE: Nutren VHP fibre	40	ROSS: Osmolite HN
11.	NESTLE: Nutren Fibre with Prebio 1	41	ROSS: Promote
12.	NESTLE: Nutren Fibre with Prebio 1.5	42	ROSS: Glucerna
13.	NESTLE: Nutrihep	43	ROSS: Nepro
14.	NESTLE: Supplements - Caloreen	44	ROSS: Suplena
15.	NOVARTIS: Compleat	45	ROSS: Pulmocare
16.	NOVARTIS: Impact	46	ROSS: Perative
17.	NOVARTIS: Impact 1.5	47	ROSS: Vital HN
18.	NOVARTIS: Isosource HN	48	ROSS: TWO Cal HN
19.	NOVARTIS: Isosource HN with fibre	49	ROSS: Oxepa
20.	NOVARTIS: Isosource VHN	50	ROSS: Optimental
21.	NOVARTIS: Isosource 1.5	51	ROSS: Ensure
22.	NOVARTIS: Novasource Renal	52	ROSS: Ensure High Protein
23.	NOVARTIS: Peptinex	53	ROSS: Ensure Plus
24.	NOVARTIS: Peptinex DT	54	ROSS: Ensure Fibre
25.	NOVARTIS: Resource 2.0	55	ROSS: Supplements -Polycose powder
26.	NOVARTIS: Resource Plus	56	ROSS: Supplements -Polycose Liquid
27.	NOVARTIS: Resource Standard	57	Hormel Health: Immun-Aid
28.	NOVARTIS: Resource Diabetic	58	Hormel Health: Hepatic-Aid
29.	NOVARTIS: Tolerex	59	Other:
30.	NOVARTIS: Trauma-cal		

ORGANISM TAXONOMY

	SPECIES	SUB-SPECIES
1	Acinetobacter sp.	Baumani
2		Other specify
3	Actinomyces sp.	Other specify
4	Aeromonas sp.	Aerogenes
5		Other specify
6	Alcaligenes sp.	Dentrificans
7		Foecalis
8		Other specify
9	Bacillus sp.	Anthraxis
10		Other specify
11	Bacteroides sp.	Fragilis
12		Thetaitomicron
13		Other specify
14	Babesia sp.	Other specify
15	Bartonella sp.	Other specify
16	Borrellia sp.	Burgdoferi
17		Other specify
18	Bortetella sp.	Pertussis
19		Other specify
20	Burkholderia sp.	Cepacia
21		Mallei
22		Pseudomallei
23		Other specify
24	Campylobacter sp.	Jejuni
25		Fetus
26		Other specify
27	Capnocytophaga sp.	Other specify
28	Chlamydia sp.	Pneumoniae
29		Trachomatis
30		Other specify
31	Citrobacter sp.	Freundii
32		Koseri
33		Other specify
34	Clostridium sp	Botulism
35		Difficile
36		Perfringes
37		Tetani
38		Other specify
39	Corynobacteria sp.	Other specify
40	Coxiella sp.	Burnetti
41		Other specify
42	Diphtheroids sp.	Other specify
43	Eikenella sp.	Corrodens
44		Other specify
45	Ehrlichia sp.	Other specify
46	Enterobacter sp.	Cloacae
47		Other specify

ANTIBIOTIC TAXONOMY

1	Acyclovir	35	Clofazimine	69	Norfloxacin
2	Amantadine	36	Cloramphenicol	70	Nyastatin
3	Amikacin	37	Cloxacillin	71	Ofloxacin
4	Aminosalicylic acid	38	Cycloserine	72	Olsetamivir
5	Amoxicillin	39	Diamino-diphenyl sulphone	73	Oxacillin
6	Amoxicillin/clavulanic acid	40	Dicloxacillin	74	Penicillin
7	Amphotericin B	41	Dimenocycline	75	Pentamidine
8	Ampicillin	42	Doxycycline	76	Pipercillin
9	Ampicillin/sulbactam	43	Ertapenem	77	Pipercillin/Tazobactem
10	Anti-HIV therapy-please name:	44	Erythromycin	78	Polimyxin B
11	Azithromycin	45	Ethambutal	79	Polimyxin E
12	Aztreonam	46	Ethionamide	80	Primaquin
13	Bacitracin	47	Fluconazole	81	Pyrazinamide
14	Capreomycin	48	Flucytosine	82	Quinopristin+ Dalfopristin
15	Carbenicillin	49	Foscarnet	83	Ribavirin
16	Caspofungin	50	Ganciclovir	84	Rifabutin
17	Cefaclor	51	Gatifloxacin	85	Rifampin
18	Cefamandole	52	Gentamicin	86	Rimantadine
19	Ceftazidime	53	Imipenem/Cilastatin	87	Spectinomycin
20	Cefazolin	54	Isoniazid	88	Streptomycin
21	Cefepime	55	Itraconazole	89	Sulfadiazine
22	Cefixime	56	Kanamycin	90	Sulfamethoxazole
23	Cefoperazone	57	Ketoconazole	91	Sulfisoxazole
24	Cefotaxime	58	Levofloxacin	92	Teicoplanin
25	Cefotetan	59	Linezolid	93	Tetracycline
26	Cefoxitin	60	Meropenem	94	Ticarcillin
27	Cefprozil	61	Metronidazole	95	Ticarcillin/clavulanic acid
28	Ceftriaxone	62	Mezlocillin	96	Tigecycline
29	Cefuroxime	63	Minocycline	97	Tobramycin
30	Cephalexin	64	Moxyfloxacin	98	Trimethoprim
31	Cephalothin	65	Nafcillin	99	Trimethoprim-Sulfamethoxazole (Cotrimoxazole)
32	Ciprofloxacin	66	Nalidixic Acid	100	Trovofoxacin
33	Clarithromycin	67	Netilmycin	101	Vancomycin
34	Clindamycin	68	Nitrofurantoin	102	Voriconazole