Page by Page Guidelines for Case Report Form (CRF) completion

All pages

Subject	Guidance notes
Centre ID	Enter your allocated centre ID
Patient Study number	Enter the patient's allocated study number. Please use study numbers in sequential order.
Patient Initials	Enter initial of first, middle and family name. If no middle name put a – in the box. If the patient is a Mc or Mac put first initial, then M, then family name e.g. [S] [M] [D] for Stuart McDonald
Script	Only use black pen to enter data onto the CRF.
Corrections	If data entered is incorrect please strike through once and write the correct result alongside. Please initial and date any changes. Do not use correction fluid.
Unavailable or not applicable information	If any information is unavailable or not applicable, enter NA into the boxes. e.g. [N] [A]
Unknown information	If any information is unknown, enter UNK into the boxes. e.g. [U] [N] [K]
Written text	All freehand script to be entered in block capitals.
Leading zeros	Enter the numerical value in the boxes. If e.g. the value is 182 and there are 4 boxes to fill in, put 0 in the first box [0] [1] [8] [2]
Recording of highest and lowest values	When asked to record a highest and lowest value (e.g. white cell count) and there is only one result available, enter this one result into BOTH the highest and lowest boxes.

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Subject	Guidance notes
Time clock	The 24hr day begins at the time the patient is admitted to ITU. e.g a patient admitted at 1300hrs on 18/03/05: First 24hrs (day 1) = 1300hrs 18/03/05 to 1259hrs 19/03/05 Second 24hrs (day 2) = 1300hrs 19/03/05 to 1259hrs 20/03/05
Checklist	Tick the small boxes in the checklist table when the task has been completed. NB Co-morbidity/Risk factors can be assessed at any time point during this ICU admission. DNA and Cell Lines may be taken at any time-point during ICU admission. It is preferable to take samples as soon as practical.

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Subject	Guidance notes
CRF bar code label	Each patient has unique bar coded labels, these must not be used for more than one individual. Please ensure you attach a bar code label to page 24 of the CRF.
Consent	When the patient has not been able to consent for themselves initially, written consent must obtained as soon as the patient is competent. Once this has been done tick the box at the bottom of page 23 or 24 as applicable.
Inclusion Criteria	All boxes must be ticked Yes for the patient to qualify for study participation
Exclusion Criteria	All boxes must be ticked No for the patient to qualify for study participation

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Subject	Guidance notes
DNA blood sample	Please take sample as soon as possible after consent has been obtained. Please use the EDTA tubes provided. **Do not freeze** sample. If sample cannot be sent immediately to WHRI, please store the sample at room temperature. Tick box in table on page 2 once this has been done.
For centres collecting plasma and urine samples	Collect 1st sample as soon as possible after consent has been obtained and within the first 24hrs of ICU admission. Please aim to take day 3 and day 5 samples at the same time of day as the day 1 sample whenever possible. Aliquot samples and freeze at –20°C to –80°C
For centres collecting cell line sample	Sample as soon as possible after consent has been obtained. This sample should be taken at the same time as the DNA sample (but otherwise at any time during the ICU admission). Do not freeze sample. Tick box in table on page 2 once this has been done.

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Subject	Guidance notes
Ethnicity Questionnaire	Record details of biological parents and grandparents only. This data can be obtained from any family member. When there is uncertainty over biological relationships, leave this blank.

Subject	Guidance notes
Date of hospital admission	This refers to the date the patient is admitted to your hospital for this episode of illness.
Date and time of ICU admission	This refers to the date the patient is admitted to your ICU for this episode of illness.
Temperature ºC	Tympanic, rectal and blood temperature is acceptable.
Haematocrit (%)	Take this value from main hospital laboratory result. Results may be taken from arterial blood gases if the blood gas analyser undergoes formal quality control.
Mean BP Systolic BP	May use arterial and non-invasive blood pressure results, but it is preferable to use arterial line values.
"Adequate" Fluid resus	Please use your clinical judgement to decide as to whether fluid resuscitation was adequate.
Dopamine, Epinephrine, Norepinephrine	Round the dose to 3 significant figures. Only record infusions, not stat doses.
RS/Acid-Base MV	MV = mechanical ventilation
Respiratory rate	If the patient is breathing spontaneously in addition to mandatory mechanical ventilation, enter the **total** respiratory rate (lowest and highest).
PaO2	Please enter ABG values in kPa. To convert mmHg to kPa divide the mmHg value by 7.5
Associated PaCO2	Enter the value that is associated with the lowest PaO2. Please enter ABG values in kPa.
Associated FiO2	Enter the value that is associated with the lowest PaO2.
Base excess/deficit	Take the result from the blood gas sample or laboratory value.
Blood lactate	Take the result from the blood gas sample or laboratory value.

Subject	Guidance notes
AST or ALT	Enter highest ALT or highest AST
Systemic anti-coagulation	This refers to Warfarin or Heparin in anti-coagulant doses at any time when the blood samples were drawn. This does include Heparin used in renal replacement therapies such as haemofiltration. This does not include subcutaneous Heparin.
Glasgow coma score	Enter the best actual GCS if known; otherwise enter the estimated best GCS. Use the latest GCS prior to sedation or intubation. If the best GCS is higher than this on subsequent days enter the higher score. Whenever possible use the actual (non-sedated/intubated)score.
Urine output	If the urine collection period is less than 24hrs calculate the volume that would have been collected over a full 24hrs. e.g. If 500mls urine was collected over 8 hrs, this would approximate to 1500mls over 24hrs.
Renal Support	This is haemofiltration, haemodialysis or peritoneal dialysis.
Serum electrolytes	Use the results from the arterial blood gases (ABG's) or main hospital laboratory.
CXR	Lobar distribution is one that conforms to the anatomical distribution of an AP radiograph of the chest.

Subject	Guidance notes
2nd experienced clinician	Please tick box

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Subject	Guidance notes
Charleson Co-morbidity and infection risk factors	This refers to illness PRIOR to this hospital admission.
Recording of co-morbidity	Please tick as many boxes as apply

Temperature ºC	Tympanic, rectal and blood temperature is acceptable.
Mean BP Systolic BP	May use arterial and non-invasive blood pressure results, but it is preferable to use arterial line values.
"Adequate" Fluid resus	Please use your clinical judgement to decide as to whether fluid resuscitation was adequate.
Dopamine, Epinephrine, Norepinephrine	Round the dose to 3 significant figures. Only record infusions, not stat doses.
RS/Acid-Base MV	MV = mechanical ventilation
Respiratory rate	If the patient is breathing spontaneously in addition to mandatory mechanical ventilation, enter the **total** respiratory rate (lowest and highest).
PaO2	Please enter ABG values in kPa. To convert mmHg to kPa divide the mmHg value by 7.5
Associated FiO2	Enter the value that is associated with the lowest PaO2.
Base excess/deficit	Take the result from the blood gas sample or laboratory value.

Subject	Guidance notes
AST or ALT	Enter highest ALT or highest AST
Systemic anti-coagulation	This refers to Warfarin or Heparin in anti-coagulant doses at any time when the blood samples were drawn. This does include Heparin used in renal replacement therapies such as haemofiltration. This does not include subcutaneous Heparin.
Glasgow coma score	Enter the best actual GCS if known; otherwise enter the estimated best GCS. Use the latest GCS prior to sedation or intubation. If the best GCS is higher than this on subsequent days enter the higher score. Whenever possible use the actual (non-sedated/intubated)score.
Urine output	If the urine collection period is less than 24hrs calculate the volume that would have been collected over a full 24hrs. e.g. If 500mls urine was collected over 8 hrs, this would approximate to 1500mls over 24hrs.
Renal Support	This is haemofiltration, haemodialysis or peritoneal dialysis.
CXR	Lobar distribution is one that conforms to the anatomical distribution of an AP radiograph of the chest.
Comments	Please write any script in block capitals.

Temperature ºC	Tympanic, rectal and blood temperature is acceptable.
Mean BP Systolic BP	May use arterial and non-invasive blood pressure results, but it is preferable to use arterial line values.
"Adequate" Fluid resus	Please use your clinical judgement to decide as to whether fluid resuscitation was adequate.
Dopamine, Epinephrine, Norepinephrine	Round the dose to 3 significant figures. Only record infusions, not stat doses.
RS/Acid-Base MV	MV = mechanical ventilation
Respiratory rate	If the patient is breathing spontaneously in addition to mandatory mechanical ventilation, enter the **total** respiratory rate (lowest and highest).
PaO2	Please enter ABG values in kPa. To convert mmHg to kPa divide the mmHg value by 7.5
Associated FiO2	Enter the value that is associated with the lowest PaO2.
Base excess/deficit	Take the result from the blood gas sample or laboratory value.

Subject	Guidance notes
AST or ALT	Enter highest ALT or highest AST
Systemic anti-coagulation	This refers to Warfarin or Heparin in anti-coagulant doses at any time when the blood samples were drawn. This does include Heparin used in renal replacement therapies such as haemofiltration. This does not include subcutaneous Heparin.
Glasgow coma score	Enter the best actual GCS if known; otherwise enter the estimated best GCS. Use the latest GCS prior to sedation or intubation. If the best GCS is higher than this on subsequent days enter the higher score. Whenever possible use the actual (non-sedated/intubated)score.
Urine output	If the urine collection period is less than 24hrs calculate the volume that would have been collected over a full 24hrs. e.g. If 500mls urine was collected over 8 hrs, this would approximate to 1500mls over 24hrs.
Renal Support	This is haemofiltration, haemodialysis or peritoneal dialysis.
CXR	Lobar distribution is one that conforms to the anatomical distribution of an AP radiograph of the chest.

Temperature ºC	Tympanic, rectal and blood temperature is acceptable.
Mean BP Systolic BP	May use arterial and non-invasive blood pressure results, but it is preferable to use arterial line values.
"Adequate" Fluid resus	Please use your clinical judgement to decide as to whether fluid resuscitation was adequate.
Dopamine, Epinephrine, Norepinephrine	Round the dose to 3 significant figures. Only record infusions, not stat doses.
RS/Acid-Base MV	MV = mechanical ventilation
Respiratory rate	If the patient is breathing spontaneously in addition to mandatory mechanical ventilation, enter the **total** respiratory rate (lowest and highest).
PaO2	Please enter ABG values in kPa. To convert mmHg to kPa divide the mmHg value by 7.5
Associated FiO2	Enter the value that is associated with the lowest PaO2.
Base excess/deficit	Take the result from the blood gas sample or laboratory value.

Subject	Guidance notes
AST or ALT	Enter highest ALT or highest AST
Systemic anti-coagulation	This refers to Warfarin or Heparin in anti-coagulant doses at any time when the blood samples were drawn. This does include Heparin used in renal replacement therapies such as haemofiltration. This does not include subcutaneous Heparin.
Glasgow coma score	Enter the best actual GCS if known; otherwise enter the estimated best GCS. Use the latest GCS prior to sedation or intubation. If the best GCS is higher than this on subsequent days enter the higher score. Whenever possible use the actual (non-sedated/intubated)score.
Urine output	If the urine collection period is less than 24hrs calculate the volume that would have been collected over a full 24hrs. e.g. If 500mls urine was collected over 8 hrs, this would approximate to 1500mls over 24hrs.
Renal Support	This is haemofiltration, haemodialysis or peritoneal dialysis.
CXR	Lobar distribution is one that conforms to the anatomical distribution of an AP radiograph of the chest. For day 5 it is acceptable to use the day 4 CXR.

Temperature ºC	Tympanic, rectal and blood temperature is acceptable.
Mean BP Systolic BP	May use arterial and non-invasive blood pressure results, but it is preferable to use arterial line values.
"Adequate" Fluid resus	Please use your clinical judgement to decide as to whether fluid resuscitation was adequate.
Dopamine, Epinephrine, Norepinephrine	Round the dose to 3 significant figures. Only record infusions, not stat doses.
RS/Acid-Base MV	MV = mechanical ventilation
Respiratory rate	If the patient is breathing spontaneously in addition to mandatory mechanical ventilation, enter the **total** respiratory rate (lowest and highest).
PaO2	Please enter ABG values in kPa. To convert mmHg to kPa divide the mmHg value by 7.5
Associated FiO2	Enter the value that is associated with the lowest PaO2.
Base excess/deficit	Take the result from the blood gas sample or laboratory value.

Subject	Guidance notes
AST or ALT	Enter highest ALT or highest AST
Systemic anti-coagulation	This refers to Warfarin or Heparin in anti-coagulant doses at any time when the blood samples were drawn. This does include Heparin used in renal replacement therapies such as haemofiltration. This does not include subcutaneous Heparin.
Glasgow coma score	Enter the best actual GCS if known; otherwise enter the estimated best GCS. Use the latest GCS prior to sedation or intubation. If the best GCS is higher than this on subsequent days enter the higher score. Whenever possible use the actual (non-sedated/intubated)score.
Urine output	If the urine collection period is less than 24hrs calculate the volume that would have been collected over a full 24hrs. e.g. If 500mls urine was collected over 8 hrs, this would approximate to 1500mls over 24hrs.
Renal Support	This is haemofiltration, haemodialysis or peritoneal dialysis.
CXR	Lobar distribution is one that conforms to the anatomical distribution of an AP radiograph of the chest. For day 7 it is acceptable to use the day 5 CXR.

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Subject	Guidance notes
Antibiotics	Record antibiotics given only for CAP or FP in the first 7 days of ICU stay.
Start date & time	Enter date and time that the first dose was given (this may have been prior to ICU admission)
End day	If antibiotics continue past ICU discharge leave end date blank and tick the box "antibiotics continued after ICU discharge" on page 21.
AB's stopped and restarted	Use the "other" boxes to record a second course of AB's on page 21.
Stat doses	Enter the first stat dose in the appropriate box (on page 20) For multiple stat doses, use the "other" boxes to enter details (on page 21).
Antibiotics	This is intravenous or oral antibiotics.
Antibiotics administered pre ICU admission.	If the information is readily available, please record any antibiotics given for either FP or CAP, prior to admission to intensive care e.g. by General Practitioner or inter-operatively.

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Subject	Guidance notes
Antibiotics prescribed but not listed on prior page or given in repeat courses	This still applies to antibiotics given for CAP or FP during the 1st 7 days of ICU admission.
"other " (state)	Enter the name of the antibiotic
Start date & time	Enter date and time that the first dose was given (this may have been prior to ICU admission)
AB's stopped and restarted	Use the "other" boxes to record a second course of AB's.
Stat doses	Enter the first stat dose in the appropriate box (page 20) For multiple stat doses, use the "other" boxes to enter details (page 21)
Antibiotics	This is intravenous or oral antibiotics.

Subject	Guidance notes
Additional Infection Audit	Please tick box if patient acquired another infection at any time during this ICU admission. This does not require detailed meticulous examination of previous records, just a report of major episodes of ICU acquired infection.
Other specific "Sepsis Therapies"	Please tick any boxes which apply.
Duration of organ support	Please estimate the cumulative total. e.g. if the patient receives AHF for a total of 5 days in a 10 day admission period, enter 5 for number of days of renal support.
Mechanical respiratory support	Includes NIV, mask CPAP
Renal support	Includes haemofiltration, diafiltration, dialysis.

Subject	Guidance notes
Patient confirmation of consent	Please tick Yes box if consent originally obtained from legal representative and confirmed by patient prior to their discharge from ICU.

Subject	Guidance notes
Bar Code Label	**Please ensure that a bar code label is attached to the top of this page**
Final discharge and outcome data	Please retain this form locally until the 6-month follow-up is completed (or until patient's discharge or death if this occurs before the 6 month time point).
Hospital Discharge	This is the date that the patient leaves your hospital (or transferred to other hospital) following this episode of illness.
Patient confirmation of consent	Please tick Yes box if consent originally obtained from legal representative and confirmed by patient prior to their discharge from hospital. Please ignore this if patient has already confirmed consent during ICU admission.
Return part 2	Please ensure all data entry is complete, then photocopy form and send the **original** to the co-ordinator in Oxford, using the pre-paid, pre-addressed envelope. Please retain the photocopy with Part 1 and any copies of consent forms locally in your site files.