**BALANCE**, Australian site study monitoring worksheet – for study monitor to complete

**Site Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Participant Study Number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date of patient’s enrolment \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Start Time \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ End time \_\_\_\_\_\_\_\_\_\_\_\_ Total Time taken \_\_\_\_\_\_\_\_\_\_\_\_\_\_**

1. **Index Culture Data**

What will be verified: Index blood culture and susceptibilities for which patient was enrolled into the study.

SDV Checklist and Outcome –

* Sample source for the culture is blood (i.e. report is for a ‘blood culture’) ○ Y ○ N
* Collection date & time match CRF ○ Y ○ N
* Bacterial species matches CRF ○ Y ○ N
* Antibiotic susceptibility matches CRF ○ Y ○ N
* What source document(s) were provided (tick all that apply)

○ None ○Pathology Reports Supplementary Reports Other sources (emails/screenshots from laboratory system etc.)

Notes (if any) -

How many minutes did it take to complete this SDV…..

1. **Antimicrobial Use Data**

What will be verified: Antimicrobials data recorded on CRF matches with clinical records.

SDV checklist and outcome

* Source document(s) provided ○ Y ○ N
* Antimicrobials administered match CRF ○ Y ○ N
* Antimicrobial dose matches CRF ○ Y ○ N
* Start and stop date/time match CRF ○ Y ○ N
* How many different source documents were provided/viewed to verify this data…………………
* How long did it take to complete this SDV….. ……….(minutes)

Notes (if any) -

1. **30 day outcome**

What will be verified: All positive blood cultures done before day 30 recorded on CRF match with patient records.

SDV checklist and outcome

* Source document(s) provided ○ Y ○ N ○ NA (no further positive cultures recorded)
* Record the total number of additional samples that were recorded (and required SDV)…
* Sample source for cultures matches CRF (blood, urine sputum etc.) ○ Y ○ N
* Collection date & time match CRF ○ Y ○ N
* Bacterial species matches CRF ○ Y ○ N
* Antibiotic susceptibility in the report matches CRF ○ Y ○ N
* How many different source documents were provided/viewed to verify this data……………….?
* How long did it take to complete this SDV…..? ……….(minutes)

Notes (if any) -

1. **90 Day Outcome Data (All patients)**

What will be verified: Hospital discharge date and vital status at discharge, status at day 90 as per medical record or telephonic record to the patient/family by research team.

SDV checklist and outcome

* Hospital discharge date matches CRF ○ Y ○ N
* Vital status at discharge matches CRF ○ Y ○ N
* Vital status at day 90+ matches CRF ○ Y ○ N
* 90d vital status document type: ○ Not provided ○ Clinical record ○ Record of research team contact
* How many different source documents were provided/viewed to verify this data……………….?
* How long did it take to complete this SDV…..? ……….(minutes)

Notes (if any) -

1. **ICU Outcome Data (Only for ICU patients)**

What will be verified: Date of discharge from ICU, vital status at the time of ICU discharge and readmission to ICU.

SDV checklist and outcome

* Source document(s) provided ○ Y ○ N
* ICU Discharge date matches CRF ○ Y ○ N
* Mechanical ventilation start and stop dates match CRF ○ Y ○ N
* Vital status at ICU discharge matches CRF ○ Y ○ N
* How many different source documents were provided/viewed to verify this data……………….?
* How long did it take to complete this SDV….. ……….(minutes)

Notes (if any) –

1. Number of errors that needed correction on CRF

a.) <5

b.) 5-10

c.) 10-20

d.) >20

5. ADDITIONAL COMMENTS\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Name of monitor:**

**Signature of monitor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_**