TITRe2 A1

PATIENT ASSESSMENT FOR TRIAL ELIGIBILITY & CONSENT CHECKLIST

Centre Code ☐☐☐ **Patient Name** _____ **Patient Study ID** ☐☐☐☐☐☐

CONFIRMATION OF TRIAL ELIGIBILITY

	Yes	No		Yes	No
Aged ≥ 16 years	☐	■	Critical limb ischaemia?	■	☐
Undergoing cardiac surgery?	☐	■	Undergoing emergency surgery?	■	☐
System of beliefs prevents them from having blood and blood products (e.g. Jehovah's Witness)?	■	☐	Currently participating in any other interventional clinical study?	■	☐
Congential or acquired platelet, red cell or clotting disorder?	■	☐	Patient able to give fully informed consent for the study (e.g. no learning or language difficulties)?	☐	■
Ongoing or recurrent sepsis?	■	☐			

NOTE: IF ANY ■ ARE TICKED THEN PATIENT IS NOT ELIGIBLE FOR THE TRIAL

- If patient is *not* eligible, please enter reason(s) for ineligibility to the screening log *(destroy this page if completed or partially completed)*.
- If patient is eligible and wishes to take part, obtain written consent before proceeding.

AFTER PATIENT HAS CONSENTED:

Once consent is obtained, please ensure the following are carried out with patient present:

Remind the patient about the 3-month follow-up questionnaire and record patient's phone number *(include dialling code)*: _____

Please record patient's address and postcode *(for postal questionnaire)* _____

_____

Postcode __ __ __ __ __ __ __

	Yes	No
Does the patient wish to be informed of the results of the study once it has ended?	☐	☐
Does the patient wish to know their treatment allocation (if randomised) once the study has ended?	☐	☐
GP letter sent to the patient's GP?	☐	☐

Checklist of tasks for site to complete at registration:

Study registration sticker & blue clip attached and randomisation form added to patient's notes?	☐	Patient given a *copy* of their signed consent form to keep?	☐
Patient given baseline EQ5D booklet to complete prior to surgery?	☐	Patient given a copy of the PIS to keep?	☐

This section can be completed without patient present (tick box when task is complete):

Original signed patient consent form filed in patient's CRF folder	☐	Copy of the sent GP letter filed in patient's CRF folder	☐
		Copy of the GP letter filed in patient's notes	☐
Copy of the signed patient consent form filed in patient's notes	☐	Copy of the Patient Information Sheet filed in patient's notes	☐
Fax the signed patient consent form to the co-ordinating centre in Bristol (0117 342 3288)	☐	Details of patient's consent added to screening log	☐

Name of person completing form* (capitals) _____ Signature of person completing form _____ Date completed *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

PATIENT DETAILS AT REGISTRATION –all consented patient (con)

Centre Code | **Patient Name** | **Patient Study ID**

PATIENT AND GP DETAILS

Date of Birth __ __ /__ __ /__ __ __ __ *dd/mm/yyyy*

Sex: Male ☐ Female ☐

Height ☐☐☐ cm

Weight ☐☐☐.☐ kg

GP Name

GP Address

GP Postcode __ __ __ __ __ __ __

NHS Number __ __ __ __ __ __ __ __ __ __

OR

CHI Number *(for Scottish centres)* __ __ __ __ __ __ __ __ __ __

Operative priority: Elective ☐ Urgent ☐

Baseline (pre-operative) blood tests:

Haemoglobin (Hb) ☐☐.☐ g / dL Haematocrit (Hct) ☐☐.☐ % Creatinine ☐☐☐☐ µmol / L

EUROSCORE

LV function: Good *(> 50%)* ☐ Moderate *(30 - 50%)* ☐ Poor *(< 30%)* ☐

	Yes	No
Surgery on thoracic aorta *(for disorder of ascending, arch or descending aorta)*	☐	☐
Chronic pulmonary disease / asthma? *(longterm use of bronchodilators or steroids)*	☐	☐
Extracardiac arteriopathy? *(claudication, carotid occlusion or > 50% stenosis , previous or planned surgery on the abdominal aorta, limb arteries or carotids)*	☐	☐
Neurological dysfunction? *(disease severely affecting ambulation or day-to-day functioning)*	☐	☐
Previous cardiac surgery? *(pericardium opened)*	☐	☐
Active endocarditis? *(on antibiotics)*	☐	☐
Critical preoperative state? *(VT, VF, aborted sudden death, pre-operative cardiac massage, IPPV, inotropes, IABP or ARF (oliguria < 10 ml/h))*	☐	☐
Unstable angina? *(IV nitrates until arrival in operating theatre)*	☐	☐
Recent MI? *(< 90 days pre-surgery)*	☐	☐
Pulmonary hypertension? *(Systolic PA > 60 mmHg)*	☐	☐
Postinfarct septal rupture?	☐	☐

Name of person completing form* (capitals) | Signature of person completing form | Date completed *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) | Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

PATIENT DETAILS AT REGISTRATION – (con)

Centre Code ☐☐☐ **Patient Name** _____ **Patient Study ID** ☐☐☐☐☐☐

OTHER MEDICAL HISTORY

NYHA class: *(Tick one only)*

- I ☐ *No symptoms and no limitations in ordinary physical activity.*
- II ☐ *Mild symptoms and slight limitation during ordinary activity. Comfortable at rest.*
- III ☐ *Marked limitation in activity due to symptoms, even during less-than-ordinary activity. Comfortable only at rest.*
- IV ☐ *Severe limitations. Experiences symptoms even while at rest.*

Angina class (CCS): *(Tick one only)*

- 0 ☐ *No angina. Asymptomatic.*
- I ☐ *Angina with strenuous / prolonged exertion. Ordinary activity such as walking does not cause angina.*
- II ☐ *Slight limitation of activity. Events such as rapid walking or climbing stairs, emotional stress cause angina.*
- III ☐ *Marked limitation of activity. Walking or climbing stairs in normal conditions at normal pace cause angina.*
- IV ☐ *Inability to carry out any physical activity without discomfort, anginal symptoms may be present at rest.*

Diabetes?	Diet ☐	Oral medication ☐	Insulin ☐	No ☐			
Pacemaker?	Permanent ☐	Temporary ☐	No ☐				
Heart rhythm?	Heart block ☐	Atrial fibrillation / flutter ☐	Sinus ☐				
Smoker?	Yes ☐	Ex-smoker (>1 month) ☐	No ☐	*NB. Ex-smoker (<1 month) is considered as a smoker*			
Haemofiltration / dialysis?	Yes ☐	No ☐					
CVA / TIAs?	Yes ☐	No ☐					
Coronary disease?	Single ☐	Double vessel ☐	Triple vessel ☐	None ☐	Not investigated ☐		
Disease in left main stem *(> 50% stenosis)*?	Yes ☐	No ☐					

	Yes	No
IV nitrates until theatre?	☐	☐
Unfractionated heparin intravenously within 6 h of surgery?	☐	☐
Low molecular weight heparin (clexane, tinzaparin) at therapeutic dose within 12 h preoperatively?	☐	☐
Inotropes until theatre?	☐	☐
Aspirin within 5 days pre-operatively?	☐	☐
Clopidogrel within 5 days pre-operatively?	☐	☐

Name of person completing form* (capitals) _____

Signature of person completing form _____

Date completed *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

TITRe2

A4

RANDOMISATION FORM

Centre Code ☐☐☐ **Patient Name** _____ **Patient Study ID** ☐☐☐☐☐☐

SECTION 1: TRIAL ELIGIBILITY AT RANDOMISATION

Has patient's haemoglobin fallen to < 9.0 g/dL OR the haematocrit fallen to < 27? **Yes** ☐ **No** ☐
(Please randomise patient in either of the above cases)

NOTE: If **NO** is ticked, then patient is **NOT ELIGIBLE** for randomisation.

Date and time Hb < 9.0 g/dL ***OR*** Hct < 27 recorded: __ __ /__ __ /__ __ __ __ *dd/mm/yyyy* __ __ : __ __ *(24 hour clock)*

Qualifying Hb value ☐☐.☐ g / dL OR Qualifying Hct value ☐☐.☐ %

If patient is eligible for randomisation, please enter date of birth, hospital number and 'operation type' below (this information is required for randomisation) and then complete randomisation at: http://www.sealedenvelope.com/titre2

Date of Birth *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

Hospital number _____

Operation type: CABG only ☐ CABG and Valve ☐ Valve only ☐ Other ☐

SECTION 2: AFTER RANDOMISATION, COMPLETE THE SECTION BELOW:

Randomisation number (generated by computer at randomisation): ☐☐☐☐☐

Treatment allocation:

Group 1: 'Liberal' *(transfuse if Hb < 9.0 g / dL **OR** Hct < 27)* ☐

Group 2: 'Restrictive' *(transfuse if Hb <7.5 g / dL **OR** Hct < 22)* ☐

Please ensure the correct colour coded clip (indicating treatment allocation) is attached to be visible on patient's chart or notes as follows:

*Please tick **ONE** of the below when completed:*

Group 1: 'Liberal' - **GREEN LABEL** ☐ OR Group 2: 'Restrictive' - **ORANGE LABEL** ☐

Name of person who randomised patient *(please print)*: _____

Is the clinician responsible for this patient at time of randomisation willing for the patient to be treated at this time in accordance with the allocated protocol group? * Yes ☐ No ☐

Name of clinician consulted for decision *(please print)* _____

Grade of clinician consulted for decision: Consultant ☐ Registrar ☐ Other ☐

Note to person randomising: please file this completed Randomisation Form in the patient's notes for the attention of the research co-ordinator.

*Note to research co-ordinator: If responsible clinician not in agreement with patient being treated according to protocol at this time , please ensure the relevant form in CRF Section E is completed to document this

Name of person completing form* (capitals) _____ Signature of person completing form _____ Date completed *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

POST-OPERATIVE INFORMATION & DAILY CHECKS FOR ALL PATIENTS - (con)

Centre Code ☐☐☐ **Patient Name** _____ **Patient Study ID** ☐☐☐☐☐☐

OPERATION TYPE:

CABG only ☐ Valve only ☐ CABG + valve ☐ Other ☐ *If other, specify:* _____

SUMMARY OF Hb, Hct AND RBC TRANSFUSION DATA FOR DURATION OF HOSPITAL STAY

Complete this table **daily** for **ALL CONSENTED PATIENTS** for **each day** the patient was **in hospital after their operation up to and including day 10.** *NB: Day 0 is the day of the patient's operation.*

		Please complete both Hb and Hct if recorded *(indicate with NR if not recorded on any day)*		RBC transfusion received?	
Day	**Date** (dd/mm/yyyy)	Lowest Hb *(g/dL)*	Lowest Hct *(%)*	Yes	No
0 *	____ / ____ / _____			☐	☐
1	____ / ____ / _____			☐	☐
2	____ / ____ / _____			☐	☐
3	____ / ____ / _____			☐	☐
4	____ / ____ / _____			☐	☐
5	____ / ____ / _____			☐	☐
6	____ / ____ / _____			☐	☐
7	____ / ____ / _____			☐	☐
8	____ / ____ / _____			☐	☐
9	____ / ____ / _____			☐	☐
10	____ / ____ / _____			☐	☐

** Note: for day 0 (i.e. day of surgery), complete post-op details only*

*For **randomised** participants **use this form and B2 to monitor breaches of protocol** allocation (giving or withholding RBC in contravention of allocated group). If there are any instances of this, complete relevant form (in Section E)*

Please complete the following for ALL patients at discharge:

Status at end of operation *(complete post-operatively)* Alive ☐ Dead ☐

Patient status at discharge from cardiac surgery unit Alive ☐ Dead ☐

TOTAL BLOOD PRODUCTS USED DURING HOSPITAL STAY

Total blood products given intra-operatively and post-operatively (units) *(if none, enter 0)*

RBC ☐☐ FFP ☐☐ Platelets ☐☐ Cryoprecipitate ☐☐ Activated Factor VII Yes ☐ No ☐

Beriplex Yes ☐ No ☐

Name of person completing form* (capitals) _____ Signature of person completing form _____ Date completed *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

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TITRe2 B2

RBC TRANSFUSION FORM - randomised patients only (rand)

Centre Code ☐☐☐ **Patient Name** _____ **Patient Study ID** ☐☐☐☐☐☐

PLEASE COMPLETE THIS SECTION DAILY FOR EACH RBC UNIT TRANSFUSED *(Post-op—only one RBC unit should be transfused then recheck the Hb/Hct before transfusing another unit unless there are clear clinical reasons to do otherwise.)*

Did the patient receive any RBC transfusions during their stay? Yes ☐ No ☐

*If **Yes**, complete one row per unit in table below for each unit transfused (include all RBC given intra-operatively, post-operatively and for any re-operations).*

If more than 10 RBC units are transfused, use extension form H2 for additional units.

Unit	Unit Batch No	Date and time of transfusion *dd/mm/yyyy 24 hour clock*	Reason (use code from table below)	Only complete cells below if 'Reason for transfusion given' is "Per protocol" (code F): Date and time of breach that triggered prescription *dd/mm/yyyy 24 hour clock*	Hb/Hct at "trigger" breach: Hb	Hct	RBC prescribed <24 hours since "trigger" breach: Yes	No	*How many breaches occurred since randomisation/ last transfusion, before blood was prescribed?
1		____/____/____ __ __ : __ __		____/____/____ __ __ : __ __					
2		____/____/____ __ __ : __ __		____/____/____ __ __ : __ __					
3		____/____/____ __ __ : __ __		____/____/____ __ __ : __ __					
4		____/____/____ __ __ : __ __		____/____/____ __ __ : __ __					
5		____/____/____ __ __ : __ __		____/____/____ __ __ : __ __					
6		____/____/____ __ __ : __ __		____/____/____ __ __ : __ __					
7		____/____/____ __ __ : __ __		____/____/____ __ __ : __ __					
8		____/____/____ __ __ : __ __		____/____/____ __ __ : __ __					
9		____/____/____ __ __ : __ __		____/____/____ __ __ : __ __					
10		____/____/____ __ __ : __ __		____/____/____ __ __ : __ __					

Code	Reason for transfusion given:	Code	Reason for transfusion given:
A	Intra-operatively *(no E1 or E2 needed)*	D	Pre-randomisation (post-op) *(complete Note To File)*
B	Re-operation *(no E1 or E2 needed)*	E	In breach of protocol *(complete form E1 for each unit)*
C	Treatment according to protocol discontinued *(check G1 completed, no E1 or E2 needed)*	F	Per protocol *(*complete E2 for each breach recorded in the final column)*

Name of person completing form* (capitals) _____ Signature of person completing form _____ Date completed *(dd/mm/yyyy)* __ __/__ __/__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __/__ __/__ __ __ __

** Names must appear on the site signature & delegation log*

TITRe2 C1

DETAILS OF PERI-OPERATIVE PERIOD - (rand)

Centre Code | **Patient Name** | **Patient Study ID**

OPERATION DETAILS

Responsible consultant surgeon (initials)

First Operator (initials)

Date of operation *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

Start of operation *(time entered theatre)* *(24 hour clock)* __ __ : __ __

End of operation (time) *(24 hour clock)* __ __ : __ __

Lowest Hct during surgery . % Unrecorded

CPB used? Yes No *If CPB used:* Total bypass min

Cumulative cross-clamp time min

Myocardial protection used: Blood Crystalloid Other N/A

No of distal coronary anastomoses:

Valve(s) replaced / repaired:

Aortic	Yes	No
Mitral	Yes	No
Tricuspid	Yes	No
Pulmonary	Yes	No

Harvest site(s):

Right arm	Yes	No
Left arm	Yes	No
Right leg	Yes	No
Left leg	Yes	No
LIMA	Yes	No
RIMA	Yes	No
Other	Yes	No

Blood saving techniques: Tranexamic acid Yes No

Trasylol Yes No

Cell Saver Yes No

POST-OPERATIVE DETAILS

Total chest tube drainage at 4 h ml

Total chest tube drainage at 12 h ml

Was post-op cell salvage used? Yes No

RE-OPERATION DETAILS *(Enter details of 1st re-operation below, for more than 1 re-operation , complete H5)*

How many times was chest re-opened (at any time) during hospital stay? *(if none, enter 0)* *If **>0**, complete below ± H5*

Reason why chest was re-opened *(tick all that apply)*: Bleeding Cardiovascular instability Infection Other

Date of re-operation *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

Re-op start time *(24 hour clock)* __ __ : __ __

Re-op end time *(24 hour clock)* __ __ : __ __

HIGHEST CREATININE ON EACH POST-OPERATIVE DAY OF HOSPITAL STAY *(Day 1 is the 1st day after operation)*

Please collect for 10 days post-op.

Day 1:	Creatinine:	µmol / L			
Day 2:	Creatinine	µmol / L	N/A		
Day 3:	Creatinine:	µmol / L	N/A		
Day 4:	Creatinine:	µmol / L	N/A		
Day 5:	Creatinine:	µmol / L	N/A		
Day 6:	Creatinine:	µmol / L	N/A		
Day 7:	Creatinine:	µmol / L	N/A		
Day 8:	Creatinine:	µmol / L	N/A		
Day 9:	Creatinine:	µmol / L	N/A		
Day 10:	Creatinine:	µmol / L	N/A		

Name of person completing form* (capitals) ---------- Signature of person completing form ---------- Date completed *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) ---------- Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

TITRe2 C2

ASEPSIS ASSESSMENT DAY 3 - (rand)

Centre Code | **Patient Name** | **Patient Study ID**

ASEPSIS WOUND ASSESSMENT - Day 3

'Day 3' inspection (*If unable to complete on day 3, please complete as close to day 3 as possible)*

Date performed __ __ /__ __ /__ __ __ __ *dd/mm/yyyy*

N/A - patient discharged/died by day 3 ☐

N/A - patient not randomised by day 3 ☐

	Chest		Right Arm			Left Arm			Right Leg			Left Leg			Other		
	Yes	*No*	*Yes*	*No*	*NA*	*Yes*	*No*	*NA*	*Yes*	*No*	*NA*	*Yes*	*No*	*NA*	*Yes*	*No*	*NA*
Is the dressing or wound wet?*	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Does the wound feel hot?*	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

**Ask patient, or if unconscious, check with nursing staff*

If any of the above answers are YES, please complete wound scoring (below) for each affected wound.
(If there are more than 2 affected wounds, please print out continuation sheet Form H3 for additional space)

1st Wound being scored: Chest ☐ Right Arm ☐ Left Arm ☐ Right Leg ☐ Left Leg ☐ Other ☐

Proportion of wound affected	0%	<20%	20-39%	40-59%	60-79%	>80%		Yes	No	If Yes, please give date *(dd/mm/yyyy)*
Serous exudates	☐	☐	☐	☐	☐	☐	Antibiotics given for wound infection	☐	☐	____/____/_____
Erythema	☐	☐	☐	☐	☐	☐	Isolation of bacteria	☐	☐	____/____/_____
Purulent exudates	☐	☐	☐	☐	☐	☐	Drainage of pus under local anaesthesia*	☐	☐	____/____/_____
Separation of deep tissue	☐	☐	☐	☐	☐	☐	Drainage of pus under general anaesthesia†	☐	☐	____/____/_____

2nd Wound being scored: Chest ☐ Right Arm ☐ Left Arm ☐ Right Leg ☐ Left Leg ☐ Other ☐

Proportion of wound affected	0%	<20%	20-39%	40-59%	60-79%	>80%		Yes	No	If Yes, please give date *(dd/mm/yyyy)*
Serous exudates	☐	☐	☐	☐	☐	☐	Antibiotics given for wound infection	☐	☐	____/____/_____
Erythema	☐	☐	☐	☐	☐	☐	Isolation of bacteria	☐	☐	____/____/_____
Purulent exudates	☐	☐	☐	☐	☐	☐	Drainage of pus under local anaesthesia*	☐	☐	____/____/_____
Separation of deep tissue	☐	☐	☐	☐	☐	☐	Drainage of pus under general anaesthesia†	☐	☐	____/____/_____

** including vac therapy*
† Including debridement in theatre

Name of person completing form* (capitals) _____ Signature of person completing form _____ Date completed *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

TITRe2 C3

ASEPSIS ASSESSMENT DAY 5 - (rand)

Centre Code ☐☐☐ **Patient Name** _____ **Patient Study ID** ☐☐☐☐☐☐

ASEPSIS WOUND ASSESSMENT - Day 5

'Day 5' inspection *(If unable to complete on day 5, please complete as close to day 5 as*

Date performed __ __ /__ __ /__ __ __ __ *dd/mm/yyyy*

N/A - patient discharged/died by day 5 ☐

N/A - patient not randomised by day 5 ☐

	Chest		Right Arm			Left Arm			Right Leg			Left Leg			Other		
	Yes	*No*	*Yes*	*No*	*NA*	*Yes*	*No*	*NA*	*Yes*	*No*	*NA*	*Yes*	*No*	*NA*	*Yes*	*No*	*NA*
Is the dressing or wound wet?*	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Does the wound feel hot?*	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

**Ask patient, or if unconscious, check with nursing staff*

If any of the above ***answers*** are YES, please complete wound scoring (below) for each affected wound.
(If there are more than 2 affected wounds, please print out continuation sheet Form H3 for additional space)

1st Wound being scored: Chest ☐ Right Arm ☐ Left Arm ☐ Right Leg ☐ Left Leg ☐ Other ☐

Proportion of wound affected	0%	<20%	20-39%	40-59%	60-79%	>80%		Yes	No	If Yes, please give date *(dd/mm/yyyy)*
Serous exudates	☐	☐	☐	☐	☐	☐	Antibiotics given for wound infection	☐	☐	____/____/_____
Erythema	☐	☐	☐	☐	☐	☐	Isolation of bacteria	☐	☐	____/____/_____
Purulent exudates	☐	☐	☐	☐	☐	☐	Drainage of pus under local anaesthesia*	☐	☐	____/____/_____
Separation of deep tissue	☐	☐	☐	☐	☐	☐	Drainage of pus under general anaesthesia†	☐	☐	____/____/_____

2nd Wound being scored: Chest ☐ Right Arm ☐ Left Arm ☐ Right Leg ☐ Left Leg ☐ Other ☐

Proportion of wound affected	0%	<20%	20-39%	40-59%	60-79%	>80%		Yes	No	If Yes, please give date *(dd/mm/yyyy)*
Serous exudates	☐	☐	☐	☐	☐	☐	Antibiotics given for wound infection	☐	☐	____/____/_____
Erythema	☐	☐	☐	☐	☐	☐	Isolation of bacteria	☐	☐	____/____/_____
Purulent exudates	☐	☐	☐	☐	☐	☐	Drainage of pus under local anaesthesia*	☐	☐	____/____/_____
Separation of deep tissue	☐	☐	☐	☐	☐	☐	Drainage of pus under general anaesthesia†	☐	☐	____/____/_____

** including vac therapy*
† Including debridement in theatre

Name of person completing form* (capitals) _____ Signature of person completing form _____ Date completed *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

TITRe2 C4

ASEPSIS ASSESSMENT DAY 8 - (rand)

Centre Code ☐☐☐ **Patient Name** _____ **Patient Study ID** ☐☐☐☐☐☐

ASEPSIS WOUND ASSESSMENT - Day 8

'Day 8' inspection *(If unable to complete on day 8, please complete as close to day*

Date performed __ __ /__ __ /__ __ __ __ *dd/mm/yyyy*

N/A - patient discharged/died by day 8 ☐

N/A - patient not randomised by day 8 ☐

	Chest		Right Arm			Left Arm			Right Leg			Left Leg			Other		
	Yes	*No*	*Yes*	*No*	*NA*	*Yes*	*No*	*NA*	*Yes*	*No*	*NA*	*Yes*	*No*	*NA*	*Yes*	*No*	*NA*
Is the dressing or wound wet?*	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Does the wound feel hot?*	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

**Ask patient, or if unconscious, check with nursing staff*

If any of the above answers are YES, please complete wound scoring (below) for each affected wound.
(If there are more than 2 affected wounds, please print out continuation sheet Form H3 for additional space)

1st Wound being scored: Chest ☐ Right Arm ☐ Left Arm ☐ Right Leg ☐ Left Leg ☐ Other ☐

Proportion of wound affected	0%	<20%	20-39%	40-59%	60-79%	>80%		Yes	No	If Yes, please give date *(dd/mm/yyyy)*
Serous exudates	☐	☐	☐	☐	☐	☐	Antibiotics given for wound infection	☐	☐	____/____/_____
Erythema	☐	☐	☐	☐	☐	☐	Isolation of bacteria	☐	☐	____/____/_____
Purulent exudates	☐	☐	☐	☐	☐	☐	Drainage of pus under local anaesthesia*	☐	☐	____/____/_____
Separation of deep tissue	☐	☐	☐	☐	☐	☐	Drainage of pus under general anaesthesia†	☐	☐	____/____/_____

2nd Wound being scored: Chest ☐ Right Arm ☐ Left Arm ☐ Right Leg ☐ Left Leg ☐ Other ☐

Proportion of wound affected	0%	<20%	20-39%	40-59%	60-79%	>80%		Yes	No	If Yes, please give date *(dd/mm/yyyy)*
Serous exudates	☐	☐	☐	☐	☐	☐	Antibiotics given for wound infection	☐	☐	____/____/_____
Erythema	☐	☐	☐	☐	☐	☐	Isolation of bacteria	☐	☐	____/____/_____
Purulent exudates	☐	☐	☐	☐	☐	☐	Drainage of pus under local anaesthesia*	☐	☐	____/____/_____
Separation of deep tissue	☐	☐	☐	☐	☐	☐	Drainage of pus under general anaesthesia†	☐	☐	____/____/_____

** including vac therapy*
† Including debridement in theatre

Name of person completing form* (capitals) _____ Signature of person completing form _____ Date completed *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

TITRe2 C5

SUMMARY OF INFECTIOUS POST-OPERATIVE COMPLICATIONS - (rand)

Centre Code | **Patient Name** | **Patient Study ID**

INFECTIOUS EVENTS SUMMARY

*Please add details for **all courses of antibiotics (excluding post-op prophylaxis)** prescribed to the patient during their post-op hospital stay. Data collection is recommended on day 3, 5, 8 (if not previously discharged) and on discharge. For all courses **provide anonymised copies of the drug chart**, with patient study ID and initials, to the TITRe 2 co-ordinating centre.*

Was the patient given antibiotics at any time during their post-operative stay *(excluding prophylaxis)*? Yes ☐ No ☐ If **Yes**, how many courses? ☐

For each course of antibiotics given to the patient, please complete a section below:

1 Name of antibiotic: _____ Date and time started antibiotic: __ __ /__ __ /__ __ __ __ *dd/mm/yyyy* __ __ : __ __ *(24 hour clock)*

Were the antibiotics: Oral? ☐ IV? ☐ Duration of course: ☐☐ days

Site of suspected infection (tick all that apply): Respiratory ☐ Wound ☐ Blood ☐ Other ☐

In the 24h preceding the start of antibiotics did the patient have any of the following symptoms?

Temperature > 38°C or < 36°C?	Yes ☐	No ☐	Unrecorded ☐	
Heart rate > 90 beats per minute?	Yes ☐	No ☐	Unrecorded ☐	
Respiratory rate > 20 breaths per minute?	Yes ☐	No ☐	Unrecorded ☐	Was infection subsequently confirmed by positive culture?
$PaCO_2$ < 32 mmHg or < 4.3 kPa?	Yes ☐	No ☐	Unrecorded ☐	
WBC count > 12,000 / mm^3 or < 4,000 / mm^3?	Yes ☐	No ☐	Unrecorded ☐	Yes ☐ No ☐

2 Name of antibiotic: _____ Date and time started antibiotic: __ __ /__ __ /__ __ __ __ *dd/mm/yyyy* __ __ : __ __ *(24 hour clock)*

Were the antibiotics: Oral? ☐ IV? ☐ Duration of course: ☐☐ days

Site of suspected infection *(tick all that apply)*: Respiratory ☐ Wound ☐ Blood ☐ Other ☐

In the 24h preceding the start of antibiotics did the patient have any of the following symptoms?

Temperature > 38°C or < 36°C?	Yes ☐	No ☐	Unrecorded ☐	
Heart rate > 90 beats per minute?	Yes ☐	No ☐	Unrecorded ☐	
Respiratory rate > 20 breaths per minute?	Yes ☐	No ☐	Unrecorded ☐	Was infection subsequently confirmed by positive culture?
$PaCO_2$ < 32 mmHg or < 4.3 kPa?	Yes ☐	No ☐	Unrecorded ☐	
WBC count > 12,000 / mm^3 or < 4,000 / mm^3?	Yes ☐	No ☐	Unrecorded ☐	Yes ☐ No ☐

3 Name of antibiotic: _____ Date and time started antibiotic: __ __ /__ __ /__ __ __ __ *dd/mm/yyyy* __ __ : __ __ *(24 hour clock)*

Were the antibiotics: Oral? ☐ IV? ☐ Duration of course: ☐☐ days

Site of suspected infection *(tick all that apply)*: Respiratory ☐ Wound ☐ Blood ☐ Other ☐

In the 24h preceding the start of antibiotics did the patient have any of the following symptoms?

Temperature > 38°C or < 36°C?	Yes ☐	No ☐	Unrecorded ☐	
Heart rate > 90 beats per minute?	Yes ☐	No ☐	Unrecorded ☐	
Respiratory rate > 20 breaths per minute?	Yes ☐	No ☐	Unrecorded ☐	Was infection subsequently confirmed by positive culture?
$PaCO_2$ < 32 mmHg or < 4.3 kPa?	Yes ☐	No ☐	Unrecorded ☐	
WBC count > 12,000 / mm^3 or < 4,000 / mm^3?	Yes ☐	No ☐	Unrecorded ☐	Yes ☐ No ☐

Name of person completing form* (capitals) _____ Signature of person completing form _____ Date completed *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

TITRe2 C6

SUMMARY OF ISCHAEMIC POST-OPERATIVE COMPLICATIONS - (rand)

Centre Code ☐☐☐ **Patient Name** _____ **Patient Study ID** ☐☐☐☐☐☐

ISCHAEMIC EVENTS SUMMARY

*Please add details of all ischaemic events as they occur. Data collection is recommended on day 3, 5, 8 (if not previously discharged) and on discharge. Please also provide documentary evidence of verification as appropriate *.*

COMPLICATION	If yes, please complete date and time when first documented in the notes:	VERIFICATION*
Permanent stroke Yes ☐ No ☐	__ __/__ __/__ __ __ __ *dd/mm/yyyy* __ __ : __ __ *(24 hour clock)* If time is not known, please indicate time of day: AM ☐ PM ☐ Overnight ☐ Not known ☐	CT Yes ☐ No ☐ MRI Yes ☐ No ☐
Suspected myocardial infarction Yes ☐ No ☐	__ __/__ __/__ __ __ __ *dd/mm/yyyy* __ __ : __ __ *(24 hour clock)* If time is not known, please indicate time of day: AM ☐ PM ☐ Overnight ☐ Not recorded ☐	Which Troponin was measured? I ☐ T ☐ Please give highest level ☐☐☐☐.☐☐ *ng/L* µg/L* ng/ml** **delete as applicable*
Gut infarction Yes ☐ No ☐	__ __/__ __/__ __ __ __ *dd/mm/yyyy* __ __ : __ __ *(24 hour clock)* If time is not known, please indicate time of day: AM ☐ PM ☐ Overnight ☐ Not known ☐	Laparotomy Yes ☐ No ☐ Post mortem ☐ ☐
Acute kidney injury Yes ☐ No ☐	__ __/__ __/__ __ __ __ *dd/mm/yyyy* __ __ : __ __ *(24 hour clock)* If time is not known, please indicate time of day: AM ☐ PM ☐ Overnight ☐ Not known ☐	AKIN criteria Stage 1, 2 or 3 (see box below for definitions) Yes ☐ No ☐

If **Yes to Acute kidney injury,** please specify most severe stage experienced *(complete on discharge):* ☐

Stage 1: *Serum creatinine increase ≥ 0.3mg/dl (≥ 26.4µmol/l) or increase to 1.5-fold to 2-fold from baseline† OR urine output < 0.5ml/kg/h for >6 h.*
Stage 2: *Serum creatinine increase > 2-fold to 3-fold from baseline† OR urine output < 0.5 ml/kg/h for >12 h.*
Stage 3: *Serum creatinine increase >3-fold from baseline† or serum creatinine ≥ 4.0 mg/dl (≥ 354 µmol/l) with an acute increase of at least 0.5 mg/dl (44 µmol/l) OR need for renal replacement therapy (RRT) irrespective of stage at time of RRT OR urine output <0.3 ml/kg/h for 24 h or anuria for 12 h.*

† baseline refers to pre-operative serum creatinine measurement

**NB. Documentary evidence should take the form of copies of the relevant report (i.e. CT / MRI / PM / biochemistry / operation) / obs chart / copy of page in notes signed off by doctor / copy of discharge letter containing the relevant information.*
Please anonymise copies of documentation and add the patient's study ID & initials before sending to the co-ordinating centre

Name of person completing form* (capitals) _____ Signature of person completing form _____ Date completed *(dd/mm/yyyy)* __ __/__ __/__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __/__ __/__ __ __ __

** Names must appear on the site signature & delegation log*

TITRe2 C7

SUMMARY OF OTHER POST-OPERATIVE COMPLICATIONS - (rand)

Centre Code | **Patient Name** | **Patient Study ID**

SUMMARY OF OTHER COMPLICATIONS (For all re-occurrences of complications, complete H5)

Please add details of all other events listed below if / when they occur. Data collection is recommended on day 3, 5, 8 (if not previously discharged) and on discharge.

			Date and time first documented in notes		If time is unknown please indicate time of day				SAE*		Number of events
Complication* *(see TITRe 2 trial manual, section 10, for full definitions)*	Yes	No	Date *(dd/mm/yyyy)*	Time *(24 hour clock)*	*AM*	*PM*	*Overnight*	*Unknown*	Yes	No	*(enter 0 if none)*
Transient ischaemic attack											
Pancreatitis											
Intestinal obstruction/perforation											
Post-operative haemorrhage (400ml/h for 1h or 200ml/h for 4h)											
ARDS											
Re-intubation/ventilation *(if >1, use H5 to record multiple instances)*											
Tracheostomy											
Initiation of mask CPAP											
Pneumothorax requiring chest drainage											
Pleural effusion requiring drainage											
Pacing											
SVT/AF requiring treatment											
VF/VT requiring intervention											
Deep vein thrombosis											
Pulmonary embolus											
Low cardiac output requiring management (including IABP)											
Wound dehiscence requiring rewiring/treatment											
Other GI *(specify)*											
Other pulmonary *(specify)*											
Other arrhythmia *(specify)*											
Other thromboembolic *(specify)*											

Tick SAE as Yes for any complications listed that met the definition of serious, i.e. are/were life-threatening, resulted in persistent or significant disability/incapacity, prolonged hospitalisation or resulted in death.

If any complications listed above resulted in **death**, or another event not listed was serious (see box above), you **MUST** report it to the CTEU as an SAE using the forms in **Section F** within 24h of discovering the event.

Please use this box for any additional information/comments on Forms C5-C7:

Name of person completing form* (capitals) _____

Signature of person completing form _____

Date completed *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

TITRe2 D1

PATIENT DETAILS AT DISCHARGE - (rand)

Centre Code | **Patient Name** | **Patient Study ID**

PATIENT MOVEMENT BETWEEN WARDS

Date and time first admitted to CICU/HDU post-operatively: __ __ /__ __ /__ __ __ __ (dd/mm/yyyy) __ __ : __ __ (24 hour clock) N/A ☐ *(Tick N/A if not applicable)*

Date and time of extubation *(Use H5 if patient was re-extubated)*: __ __ /__ __ /__ __ __ __ (dd/mm/yyyy) __ __ : __ __ (24 hour clock) N/A* ☐ *(*i.e. N/A if patient dies whilst intubated)*

Patient discharged from CICU/HDU to: General ICU ☐ Ward ☐ Patient died ☐ Home ☐ Other ☐

Date and time first admitted to general ICU (if applicable): __ __ /__ __ /__ __ __ __ (dd/mm/yyyy) __ __ : __ __ (24 hour clock) N/A ☐

Date and time first admitted to ward (if applicable): __ __ /__ __ /__ __ __ __ (dd/mm/yyyy) __ __ : __ __ (24 hour clock) N/A ☐

If time admitted to ward not known, please indicate time of day: AM ☐ PM ☐ Overnight ☐

READMISSIONS TO CICU/HDU / GENERAL ICU / WARD *(If >2 readmissions, use H5)*

How many times was the patient readmitted? *(if none, enter 0)* ☐ *If **>0**, please complete section below ± H5, if **0**, go to status at discharge*

Date and time patient 1st readmitted to: CICU/HDU ☐ General ICU ☐ Ward ☐ __ __ /__ __ /__ __ __ __ (dd/mm/yyyy) __ __ : __ __ (24 hour clock)

Date and time patient 2nd readmitted to: CICU/HDU ☐ General ICU ☐ Ward ☐ __ __ /__ __ /__ __ __ __ (dd/mm/yyyy) __ __ : __ __ (24 hour clock)

DETAILS AT DISCHARGE

Date of discharge from cardiac surgery unit or date of death (if patient died before discharge)*: __ __ /__ __ /__ __ __ __ (dd/mm/yyyy)

Where was the patient discharged from cardiac surgery unit to?

- Other unit in this hospital ☐ → Give date of final discharge from hospital / death*: __ __ /__ __ /__ __ __ __ (dd/mm/yyyy) **OR** Ongoing ☐
- Home ☐
- Other hospital ☐ → Give name: _____
- Other ☐ → *Specify (e.g. died)*: _____

**Note: please ensure that deaths are reported on the study SAE form (Section F)*

QUESTIONS FOR PATIENT AT DISCHARGE (if possible)

Is the patient available to answer questions? Yes ☐ No ☐ ***If Yes, enter date answered & details below:*** __ __ /__ __ /__ __ __ __ (dd/mm/yyyy)

Ask: "Did you think being in one group would be better for your health than the other, if so, which?" No ☐ Group 1 *(< 9g/* ☐ Group 2 *(<7.5g/* ☐

Ask: "Do you know, or think that you know, which group you were put into?" Yes ☐ No ☐

If 'Yes', ask: "Which group do you think you were put into?" Group 1 *(< 9g/* ☐ Group 2 *(<7.5g/* ☐

Have you reminded the patient about the postal questionnaires at 6 and 12 weeks? Yes ☐ No ☐

Name of person completing form* (capitals) _____ Signature of person completing form _____ Date completed *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

TITRe2 D2

INFORMATION ABOUT MEDICATIONS- (rand)

Centre Code | **Patient Name** | **Patient Study ID**

Please complete on discharge: details of medication patients were on at baseline, in theatre /CICU/CHDU and at discharge. Do NOT include any analgesics or laxatives.

REGULAR MEDICATIONS AT BASELINE (i.e. on admission to the cardiac surgery unit, include

	Yes	No
Digoxin	☐	☐
Diuretics	☐	☐
Beta blockers	☐	☐
Calcium antagonists	☐	☐
Aspirin	☐	☐
Oral Nitrates	☐	☐
Angiotensin 2 blockers	☐	☐
ACE inhibitors	☐	☐
Warfarin	☐	☐
Clopidogrel	☐	☐

	Yes	No
Statins	☐	☐
Anti-arrhythmic	☐	☐
Heparin/clexane	☐	☐
IV GTN/nitrates	☐	☐
$FeSO_4$	☐	☐
Other please specify	☐	☐

MEDICATIONS IN THEATRE / CICU / CHDU

	Yes	No
Hydroxyethyl starch (HES/HAES)	☐	☐
Human albumin solution (HAS)	☐	☐

	Yes	No
Gelofusin	☐	☐
Inotropes	☐	☐

MEDICATIONS ON DISCHARGE (i.e. at time of discharge from cardiac surgery unit)

	Yes	No
Digoxin	☐	☐
Diuretics	☐	☐
Beta blockers	☐	☐
Calcium antagonists	☐	☐
Aspirin	☐	☐
Oral Nitrates	☐	☐
Angiotensin 2 blockers	☐	☐
ACE inhibitors	☐	☐
Warfarin	☐	☐
Clopidogrel	☐	☐

	Yes	No
Statins	☐	☐
Insulin	☐	☐
Oral anti-diabetics	☐	☐
Anti-arrhythmic	☐	☐
Heparin/clexane	☐	☐
IV GTN/nitrates	☐	☐
$FeSO_4$	☐	☐
Other please specify	☐	☐

Name of person completing form* (capitals) | Signature of person completing form | Date completed *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) | Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

TITRe2

E1

GIVING A RBC TRANSFUSION IN BREACH OF PROTOCOL - (rand)

Centre Code ☐☐☐ **Patient Name** ______________________ **Patient Study ID** ☐☐☐☐☐☐

COMPLETE A SECTION BELOW EACH TIME A UNIT OF RBC IS TRANSFUSED, IN CONTRAVENTION OF THE ALLOCATED THRESHOLD *(Use additional pages for E1 if required.)*

NB. On any given date, if >1 unit is transfused in contravention of allocated group, for the same reason and under direction of the same clinician, one section can be completed for multiple units. Otherwise, complete a separate section for each unit.

UNIT NUMBER(S) ☐ ☐ ☐ *(Enter unit number(s) listed on B2 OR H2 that this completed section applies to)*

*Immediately prior to prescription:

Hb recorded* ☐☐ . ☐ g / dL

OR Hct recorded* ☐☐ . ☐ %

Indicate why these RBC units were transfused in breach of the allocated threshold *(see E (info) for definitions)*

Excessive blood loss ☐ Sepsis ☐ Physiological indicators of oxygen debt ☐ Oversight / Error ☐

Other ☐ *Specify:* ______________________

____

Name of the clinician making decision: ______________________ N/A ☐

Job title of the clinician making decision: ______________________ N/A ☐

UNIT NUMBER(S) ☐ ☐ ☐ *(Enter unit number(s) listed on B2 OR H2 that this completed section applies to)*

*Immediately prior to prescription:

Hb recorded* ☐☐ . ☐ g / dL

OR Hct recorded* ☐☐ . ☐ %

Indicate why these RBC units were transfused in breach of the allocated threshold *(see E (info) for definitions)*

Excessive blood loss ☐ Sepsis ☐ Physiological indicators of oxygen debt ☐ Oversight / Error ☐

Other ☐ *Specify:* ______________________

____

Name of the clinician making decision: ______________________ N/A ☐

Job title of the clinician making decision: ______________________ N/A ☐

UNIT NUMBER(S) ☐ ☐ ☐ *(Enter unit number(s) listed on B2 OR H2 that this completed section applies to)*

*Immediately prior to prescription:

Hb recorded* ☐☐ . ☐ g / dL

OR Hct recorded* ☐☐ . ☐ %

Indicate why these RBC units were transfused in breach of the allocated threshold *(see E (info) for definitions)*

Excessive blood loss ☐ Sepsis ☐ Physiological indicators of oxygen debt ☐ Oversight / Error ☐

Other ☐ *Specify:* ______________________

____

Name of the clinician making decision: ______________________ N/A ☐

Job title of the clinician making decision: ______________________ N/A ☐

Name of person completing form* (capitals) ______________________

Signature of person completing form ______________________

Date completed *(dd/mm/yyyy)* __ __/__ __/__ __ __ __

Name of person entering data* (capitals) ______________________

Date data entered *(dd/mm/yyyy)* __ __/__ __/__ __ __ __

Version 3.0, 31/01/2011

** Names must appear on the site signature & delegation log*

REASONS FOR RED BLOOD CELL TRANSFUSION OUT OF PROTOCOL (FOR USE WITH FORM E1)

Reason for Red Blood Cell Transfusion

IN ACCORDANCE WITH ASSIGNED RED BLOOD CELL TRANSFUSION THRESHOLDS

Hb < 9.0 g / dL / Hct < 27 if in control group
OR
Hb < 7.5 g / dL / Hct < 22 if in restrictive group

Other indications for red blood cell transfusions (outside assigned thresholds)

EXCESSIVE BLOOD LOSS

Defined as **ONE OF** (a), (b) or (c):
(a) > 4 ml kg^{-1} h^{-1} in any one hour
(b) > 2 ml kg^{-1} h^{-1} for two consecutive hours
(c) > 5 ml kg^{-1} h^{-1} in the first four hours post-op
PLUS
MABP < 60 mmHg **OR**
MABP < 75 mmHg in hypertensive patients **OR**
Tachycardia > 120 bpm

PHYSIOLOGICAL INDICATORS OF OXYGEN DEBT

Defined as one or more of the following:
PvO_2 < 32 mmHg
O_2ER > 50%
SvO_2 < 50%

SEPSIS

Defined as culture positive or suspected infection **AND** antibiotics **AND** at least two or more of the following conditions:
Temperature > 38 °C or < 36 °C
Heart rate > 90 beats / min
Respiratory rate > 20 breaths / min or $PaCO_2$ < 32 mmHg or < 4.3 kPa
WBC count > 12,000 / mm^3 or < 4000 / mm^3

Derived from Madjdpour and Spahn, British Journal of Anaesthesia 2005; 95:33-52

TITRe2

E2

WITHHOLDING A RBC TRANSFUSION IN BREACH OF PROTOCOL - (rand)

Centre Code ☐☐☐ **Patient Name** ______________________ **Patient Study ID** ☐☐☐☐☐☐

PLEASE COMPLETE A SECTION BELOW EACH TIME A RBC TRANSFUSION IS NOT GIVEN, IN CONTRAVENTION OF THE ALLOCATED THRESHOLD *(Use additional pages for E2 if required)*

Date and time Hb / Hct fell below allocated threshold __ __/__ __/__ __ __ __ *dd/mm/yyyy* __ __ : __ __ *(24 hour clock)*

OR Breach Hb recorded ☐☐.☐ g / dL
Breach Hct recorded ☐☐.☐ %

Please give details of why the RBC transfusion was NOT given in accordance with the protocol:

Oversight / Error ☐ Clinician preference *(specify below)* ☐ Other *(specify below)* ☐

Specify: ______________________

____

Name of the clinician making decision: ______________________ N/A ☐

Job title of the clinician making decision: ______________________ N/A ☐

Date and time Hb / Hct fell below allocated threshold __ __/__ __/__ __ __ __ *dd/mm/yyyy* __ __ : __ __ *(24 hour clock)*

OR Breach Hb recorded ☐☐.☐ g / dL
Breach Hct recorded ☐☐.☐ %

Please give details of why the RBC transfusion was NOT given in accordance with the protocol:

Oversight / Error ☐ Clinician preference *(specify below)* ☐ Other *(specify below)* ☐

Specify: ______________________

____

Name of the clinician making decision: ______________________ N/A ☐

Job title of the clinician making decision: ______________________ N/A ☐

Date and time Hb / Hct fell below allocated threshold __ __/__ __/__ __ __ __ *dd/mm/yyyy* __ __ : __ __ *(24 hour clock)*

OR Breach Hb recorded ☐☐.☐ g / dL
Breach Hct recorded ☐☐.☐ %

Please give details of why the RBC transfusion was NOT given in accordance with the protocol:

Oversight / Error ☐ Clinician preference *(specify below)* ☐ Other *(specify below)* ☐

Specify: ______________________

____

Name of the clinician making decision: ______________________ N/A ☐

Job title of the clinician making decision: ______________________ N/A ☐

Name of person completing form* (capitals) ______________________
Signature of person completing form ______________________
Date completed *(dd/mm/yyyy)* __ __/__ __/__ __ __ __

Name of person entering data* (capitals) ______________________
Date data entered *(dd/mm/yyyy)* __ __/__ __/__ __ __ __

Version 3.0, 31/01/2011

** Names must appear on the site signature & delegation log*

Sponsor Ref: CS/2007/2695
REC Ref: 08/H0606/125

TITRe2

F1

SAE INITIAL REPORT FORM—Complete ONE form per SAE (rand)

Centre Code ☐☐☐

Patient Study ID ☐☐☐☐☐☐

1. PARTICIPANT DETAILS

Patient initials: ☐☐ Sex: Male ☐ Female ☐ Date of Birth: (*dd/mm/yyyy*) __ __ /__ __ /__ __ __ __

2. BRIEF DESCRIPTION OF EVENT (max 70 characters)

3. REASON FOR REPORTING EVENT AS SAE (please tick as many as apply)

	Yes	No
Resulted in death * **Please provide copy of PM report or death certificate*	☐	☐
Is / was life-threatening	☐	☐
Resulted in persistent or significant disability / incapacity	☐	☐
Required hospitalisation	☐	☐
Prolonged an ongoing hospitalisation	☐	☐
Other (*if Yes, please specify below*)	☐	☐

4. DETAILS OF ONSET AND DURATION

Date and time of onset: __ __ /__ __ /__ __ __ __ (*dd/mm/yyyy*) __ __ : __ __ (*24 hour clock*)

End date and time (if resolved): __ __ /__ __ /__ __ __ __ (*dd/mm/yyyy*) __ __ : __ __ (*24 hour clock*)

5. OUTCOME OF EVENT

Resolved, no sequelae ☐ Resolved, with sequelae * ☐ Ongoing * *(please complete and return follow-up report form within 5 days)* ☐ Died * *(give cause and PM details or Death Certificate)* ☐

**Give details:*

6. FURTHER DETAILS OF EVENT

Maximum intensity of event (up until time of initial report): Mild: an event easily tolerated by patient, causing minimal discomfort, not interfering with ☐ Moderate: an event interfering with normal everyday activities.* ☐ Severe: an event that prevents normal everyday activities.* ☐

('interfering with everyday activities' refers to activities that the patient was previously capable of *doing at that stage in their recovery)*

Full description of event, including body site, reported signs and symptoms and diagnosis where possible:

7. DETAILS OF RESEARCH INTERVENTION

Protocol allocated group: Group 1: 'Liberal' (*Hb < 9.0 g / dL **OR** HCT < 27)* ☐ OR Group 2: 'Restrictive' (*Hb <7.5 g / dL **OR** HCT < 22)* ☐

Last Hb / HCT recorded prior to onset of event: ☐☐.☐ g / dL OR ☐☐.☐ %

Has the patient received a RBC transfusion since randomisation and prior to onset of event? Yes ☐ No ☐

If **Yes**: Date and time of last RBC transfusion given before onset of event __ __ /__ __ /__ __ __ __ (*dd/mm/yyyy*) __ __ : __ __ (*24 hour clock*) Number of units given at that transfusion ☐☐

First Hb / HCT recorded after transfusion: ☐☐.☐ g / dL OR ☐☐.☐ % Tick if not available ☐

Was treatment of patient according to allocated protocol group permanently discontinued? Yes ☐ No ☐

Name of person completing form* (capitals) _____ Signature of person completing form _____ Date completed (*dd/mm/yyyy*) __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered (*dd/mm/yyyy*) __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

TITRe2 F2

SAE INITIAL REPORT FORM—Complete ONE form per SAE (rand)

Centre Code ☐☐☐

Patient Study ID ☐«s☐☐☐☐

8. ACTION TAKEN AND FURTHER INFORMATION (further space available in box 11)

Please describe action taken below:	Please record any other information relevant to assessment of case *(e.g. medical history, test results)* below:

9. RELATEDNESS *(see trial manual for definitions)*

In the opinion of the PI or delegated doctor, was the event related either to having given or having withheld a RBC transfusion?

Not related ☐ Unlikely to be related ☐ Possibly related * ☐ Probably related * ☐ Definitely related * ☐

* If one of these is selected, please indicate whether the doctor considered the event to be related to: RBC transfusion being given ☐ ***OR*** RBC transfusion being withheld ☐

10. DETAILS OF PRINCIPAL INVESTIGATOR, OR DELEGATED DOCTOR, AT THIS SITE

The completed SAE form must be signed off by the PI or other delegated doctor at the site, prior to faxing to the TITRe 2 study office.

I confirm that the contents of this form (pages F1 and F2) are accurate and complete

Name: _____ Job title / role in study: _____

Signature _____ Date: *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

11. ADDITIONAL INFORMATION *(refer to box number of this SAE form that additional information applies to)*

Box number	Further information

Name of person completing form* (capitals) _____ Signature of person completing form _____ Date completed *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

* *Names must appear on the site signature & delegation log*

Sponsor Ref: CS/2007/2695
REC Ref: 08/H0606/125

TITRe2 F3

SAE FOLLOW-UP FORM—Complete ONE form per SAE (rand)

Centre Code ☐☐☐ **Patient Study ID** ☐☐☐☐☐☐

The follow-up SAE form should be completed for:
1. All 'ongoing' SAEs (NB: follow-up reports should be provided every 5 days until SAE is resolved)
2. Any SAE for which additional relevant information has become available since the initial report (e.g. lab results, post mortem, pathology report, etc)

1. PARTICIPANT DETAILS

Patient initials ☐☐ Sex: Male ☐ Female ☐ Date of Birth *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

2. SAE DETAILS

Date of onset of SAE: __ __ /__ __ /__ __ __ __ *dd/mm/yyyy*

Date Initiaal SAE report sent to TITRe 2 Co-ordinating Centre: __ __ /__ __ /__ __ __ __ *dd/mm/yyyy*

3. FURTHER DETAILS OF EVENT

Maximum intensity of event (up until time of follow-up report):

Mild: an event easily tolerated by patient, causing minimal discomfort, not interfering with everyday activities.* ☐

Moderate: an event interfering with normal everyday activities.* ☐

Severe: an event that prevents normal everyday activities.* ☐

('interfering with everyday activities' refers to activities that the patient was previously capable of doing at that stage in their recovery)*

Full description of event, including body site, reported signs and symptoms and diagnosis where possible:

4. OUTCOME OF EVENT

Resolution date and time (once resolved) __ __ /__ __ /__ __ __ __ *dd/mm/yyyy* __ __ : __ __ *(24 hour clock)*

Resolved, no sequelae ☐

Resolved, with sequelae* ☐

Ongoing * *(please complete and return follow-up report form within* 5 days) ☐

Died * *(give cause and PM details if available)* ☐

Was treatment of patient according to allocated protocol group permanently discontinued? Yes ☐ No ☐

*Give details:

5. ADDITIONAL ACTION TAKEN AND FURTHER INFORMATION SINCE INITIAL REPORT

Describe further action taken & record any other information relevant to assessment of case *(e.g. medical history, test results)*:

6. DETAILS OF PRINCIPAL INVESTIGATOR, OR DELEGATED DOCTOR, AT THIS SITE

The completed SAE follow-up form must be signed off by the PI or delegated doctor at the site, prior to faxing to the TITRe 2 co-ordinating centre.

Name: _____ Job title / role in study: _____

I confirm that the contents of this form are accurate and complete.

Signature: _____ Date: *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

Name of person completing form* (capitals) _____ Signature of person completing form _____ Date completed *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

TITRe2 G1

DISCONTINUATION OF TREATMENT (rand) & WITHDRAWAL FORM - (con)

Centre Code | **Patient Name** | **Patient Study ID**

Has the responsible clinician decided to permanently discontinue the patient's treatment according to the allocated protocol group? Yes ☐ No ☐ If **Yes**, complete Section 1

Has the patient withdrawn consent? Yes ☐ No ☐ If **Yes**, complete Section 2

SECTION 1: DISCONTINUATION OF TREATMENT ACCORDING TO ALLOCATED PROTOCOL GROUP

Please complete this section for any patient for whom a decision has been made by the responsible consultant to permanently discontinue treatment according to the allocated protocol group, and return the form to the co-ordinating centre in Bristol immediately.

Name of clinician _____

Please give reason for discontinuation: _____

_____

_____

Date of discontinuation of protocol treatment __ __ /__ __ /__ __ __ __ *dd/mm/yyyy*

Time of discontinuation __ __ : __ *(24 hour clock)* Time not recorded ☐

Was treatment according to protocol permanently discontinued: Before surgery? ☐ After surgery but before randomisation? ☐ After randomisation? ☐

NB. Permanent discontinuation of protocol treatment due to clinician decision is NOT classed as a withdrawal from the trial. Data should still be collected for these patients according to the protocol unless the patient withdraws their consent. Please ensure all TITRe 2 clips are removed from patient's notes.

SECTION 2: WITHDRAWAL FROM TRIAL

Please complete this section for any patient withdrawing from the trial after giving consent and return it to the co-ordinating centre in Bristol immediately.

Please give reason for withdrawal (if known): _____

_____

_____

Date of withdrawal from trial __ __ /__ __ /__ __ __ __ *dd/mm/yyyy*

Time of withdrawal __ __ : __ *(24 hour clock)* Time not recorded ☐

Did the patient withdraw from the trial:

Before surgery? ☐ After surgery but before randomisation? ☐ After randomisation? ☐

Is the patient happy for data routinely collected about them by the NHS to still be collected and used in this study?

Yes ☐ No, patient withdraws all consent ☐ No, consultant no longer wants patient included ☐

Is the patient happy to participate in completion of follow-up questionnaires?

Yes ☐ No, patient withdraws all consent ☐

If YES, continue data collection from patient's medical notes according to the protocol (but do not carry out any further ASEPSIS wound inspections).

If NO, stop all data collection and return forms to the co-ordinating centre in Bristol.

Name of person completing form* (capitals) _____ Signature of person completing form _____ Date completed *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

TITRe2 **H1**

EXTENSION FOR FORM B1 (OPTIONAL DAILY CHECKS FOR ALL PATIENTS) - (con)

Centre Code ☐☐☐ **Patient Name** _ **Patient Study ID** ☐☐☐☐☐☐

LOWEST Hb, Hct AND RBC TRANSFUSION FOR EACH DAY POST-OPERATIVELY ***(extension from B1)***

Please complete the lowest Hb and Hct and whether or not the patient received a RBC transfusion for each day the patient was in hospital after their operation

		Please complete both Hb and Hct if recorded (indicate with NR if not recorded on any day)		**RBC transfusion received**	
Day	**Date** *(dd/mm/yyyy)*	**Lowest Hb** *(g/dL)*	**Lowest Hct** *(%)*	**Yes**	**No**
___				☐	☐
___				☐	☐
___				☐	☐
___				☐	☐
___				☐	☐
___				☐	☐
___				☐	☐
___				☐	☐
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___				☐	☐
___				☐	☐
___				☐	☐
___				☐	☐
___				☐	☐
___				☐	☐

For all RANDOMISED patients, please give further details of ALL RBC transfusions in Section E

For randomised participants only please use this form to monitor breaches of protocol allocation (giving or not giving transfusion in contravention of allocated group). If there are any instances of this, please complete relevant form (in Section E)

Name of person completing form* (capitals) _

Signature of person completing form _

Date completed *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

Version 4.0, 22/03/2012

** Names must appear on the site signature & delegation log*

TITRe2

H2

EXTENSION FORM FOR B2 (RBC TRANSFUSION FORM) - (rand)

Centre Code ☐☐☐ **Patient Name** ______________________________ **Patient Study ID** ☐☐☐☐☐☐

PLEASE COMPLETE THIS SECTION DAILY FOR EACH RBC UNIT TRANSFUSED *(Post-op—only one RBC unit should be transfused then recheck the Hb/Hct before transfusing another unit unless there are clear clinical reasons to do otherwise.)*

Complete one row per unit in table below for each unit transfused (include all RBC given intra-operatively, post-operatively and for any re-operations).

				Only complete cells below if 'Reason for transfusion given' is "Per protocol" (code F)					
		Date of transfusion *(dd/mm/yyyy)*	Reason (use code from table below)	Date and time of breach that triggered prescription	Hb/Hct at "trigger" breach		RBC prescribed <24 hours since "trigger" breach		*How many breaches occurred since randomisation/ last transfusion, before blood was prescribed?
Unit	Unit Batch No	Time of transfusion *(24 hour clock)*		*dd/mm/yyyy 24 hour clock*	Hb	Hct	Yes	No	
__		____/____/______ __ __ : __ __		____/____/______ __ __ : __ __					
__		____/____/______ __ __ : __ __		____/____/______ __ __ : __ __					
__		____/____/______ __ __ : __ __		____/____/______ __ __ : __ __					
__		____/____/______ __ __ : __ __		____/____/______ __ __ : __ __					
__		____/____/______ __ __ : __ __		____/____/______ __ __ : __ __					
__		____/____/______ __ __ : __ __		____/____/______ __ __ : __ __					
__		____/____/______ __ __ : __ __		____/____/______ __ __ : __ __					
__		____/____/______ __ __ : __ __		____/____/______ __ __ : __ __					
__		____/____/______ __ __ : __ __		____/____/______ __ __ : __ __					
__		____/____/______ __ __ : __ __		____/____/______ __ __ : __ __					
__		____/____/______ __ __ : __ __		____/____/______ __ __ : __ __					

Code	Reason for transfusion given:	Code	Reason for transfusion given:
A	Intra-operatively *(no E1 or E2 needed)*	D	Pre-randomisation (post-op) *(complete Note To File)*
B	Re-operation *(no E1 or E2 needed)*	E	In breach of protocol *(complete form E1 for each unit)*
C	Treatment according to protocol discontinued *(check G1 completed, no E1 or E2 needed)*	F	Per protocol *(*complete E2 for each breach that occurred before most recent breach)*

Name of person completing form* (capitals) ______________________________

Signature of person completing form ______________________________

Date completed *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) ______________________________

Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

Version 4.0, 31/01/2011

** Names must appear on the site signature & delegation log*

TITRe2 H3

EXTENSION FOR FORMS C2, C3 OR C4 (ASEPSIS ASSESSMENT) - (rand)

Centre Code | **Patient Name** | **Patient Study ID**

ASEPSIS WOUND ASSESSMENT EXTENSION FORM FROM PAGE C2, C3 OR C4

This is an extension sheet for form *(tick one)*: C2 (Day 3) ☐ C3 (Day 5) ☐ C4 (Day 8) ☐

Date performed *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

3rd Wound being scored: Chest ☐ Right Arm ☐ Left Arm ☐ Right Leg ☐ Left Leg ☐ Other ☐

Proportion of wound affected	0%	<20%	20-39%	40-59%	60-79%	>80%		Yes	No	If Yes, please give date *(dd/mm/yyyy)*
Serous exudates	☐	☐	☐	☐	☐	☐	Antibiotics given for wound infection	☐	☐	____/____/_____
Erythema	☐	☐	☐	☐	☐	☐	Isolation of bacteria	☐	☐	____/____/_____
Purulent exudates	☐	☐	☐	☐	☐	☐	Drainage of pus under local anaesthesia*	☐	☐	____/____/_____
Separation of deep tissue	☐	☐	☐	☐	☐	☐	Drainage of pus under general anaesthesia†	☐	☐	____/____/_____

4th Wound being scored: Chest ☐ Right Arm ☐ Left Arm ☐ Right Leg ☐ Left Leg ☐ Other ☐

Proportion of wound affected	0%	<20%	20-39%	40-59%	60-79%	>80%		Yes	No	If Yes, please give date *(dd/mm/yyyy)*
Serous exudates	☐	☐	☐	☐	☐	☐	Antibiotics given for wound infection	☐	☐	____/____/_____
Erythema	☐	☐	☐	☐	☐	☐	Isolation of bacteria	☐	☐	____/____/_____
Purulent exudates	☐	☐	☐	☐	☐	☐	Drainage of pus under local anaesthesia*	☐	☐	____/____/_____
Separation of deep tissue	☐	☐	☐	☐	☐	☐	Drainage of pus under general anaesthesia†	☐	☐	____/____/_____

5th Wound being scored: Chest ☐ Right Arm ☐ Left Arm ☐ Right Leg ☐ Left Leg ☐ Other ☐

Proportion of wound affected	0%	<20%	20-39%	40-59%	60-79%	>80%		Yes	No	If Yes, please give date *(dd/mm/yyyy)*
Serous exudates	☐	☐	☐	☐	☐	☐	Antibiotics given for wound infection	☐	☐	____/____/_____
Erythema	☐	☐	☐	☐	☐	☐	Isolation of bacteria	☐	☐	____/____/_____
Purulent exudates	☐	☐	☐	☐	☐	☐	Drainage of pus under local anaesthesia*	☐	☐	____/____/_____
Separation of deep tissue	☐	☐	☐	☐	☐	☐	Drainage of pus under general anaesthesia†	☐	☐	____/____/_____

** including vac therapy*
† Including debridement in theatre

Name of person completing form* (capitals) _____ Signature of person completing form _____ Date completed *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

TITRe2 H4

EXTENSION FOR FORM C1 (OPTIONAL PATIENT DETAILS AT DISCHARGE) - (rand)

Centre Code | **Patient Name** | **Patient Study ID**

«s

HIGHEST CREATININE ON EACH POST-OPERATIVE DAY OF HOSPITAL STAY ***(Randomised patients only)***

Day ___	Creatinine:		µmol / L	N/A
Day ___	Creatinine:		µmol / L	N/A
Day ___	Creatinine:		µmol / L	N/A
Day ___	Creatinine:		µmol / L	N/A
Day ___	Creatinine:		µmol / L	N/A
Day ___	Creatinine:		µmol / L	N/A
Day ___	Creatinine:		µmol / L	N/A
Day ___	Creatinine:		µmol / L	N/A
Day ___	Creatinine:		µmol / L	N/A
Day ___	Creatinine:		µmol / L	N/A
Day ___	Creatinine:		µmol / L	N/A
Day ___	Creatinine:		µmol / L	N/A
Day ___	Creatinine:		µmol / L	N/A
Day ___	Creatinine:		µmol / L	N/A
Day ___	Creatinine:		µmol / L	N/A
Day ___	Creatinine:		µmol / L	N/A
Day ___	Creatinine:		µmol / L	N/A
Day ___	Creatinine:		µmol / L	N/A
Day ___	Creatinine:		µmol / L	N/A
Day ___	Creatinine:		µmol / L	N/A
Day ___	Creatinine:		µmol / L	N/A
Day ___	Creatinine:		µmol / L	N/A
Day ___	Creatinine:		µmol / L	N/A
Day ___	Creatinine:		µmol / L	N/A
Day ___	Creatinine:		µmol / L	N/A
Day ___	Creatinine:		µmol / L	N/A
Day ___	Creatinine:		µmol / L	N/A
Day ___	Creatinine:		µmol / L	N/A
Day ___	Creatinine:		µmol / L	N/A
Day ___	Creatinine:		µmol / L	N/A

Name of person completing form* (capitals) | Signature of person completing form | Date completed *(dd/mm/yyyy)*

__ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) | Date data entered *(dd/mm/yyyy)*

__ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*

TITRe2 H5

POST-OPERATIVE EXTENSION FORM - (rand)

Centre Code [ ][ ][«] **Patient Name** _____ **Patient Study ID** [ ][«s][«][«][«][ ]

Complete Section(s) 1, 2 3, and/or 4 as necessary.
Multiple copies of this CRF can be completed if required
(e.g. for multiple re-occurrences of complications, re-intubations and/or re-admissions).

SECTION 1: RE-OPERATION DETAILS (for >1 re-operation)

Reason why chest was re-opened *(tick all that apply)*: Bleeding ☐ Cardiovascular instability ☐ Infection ☐ Other ☐

Date of re-operation *(dd/mm/yyyy)* __ __ / __ __ / __ __ __ __ Re-op start time *(24 hour clock)* __ __ : __ __ Re-op end time *(24 hour clock)* __ __ : __ __

SECTION 2: RE-INTUBATION & RE-EXTUBATION

Date/time of re-intubation __ __ /__ __ /__ __ __ __ *dd/mm/yyyy* __ __ : __ __ *(24 hour clock)*

Date/time of re-extubation __ __ /__ __ /__ __ __ __ *dd/mm/yyyy* __ __ : __ __ *(24 hour clock)* Re-extubation N/A* ☐ **Patient died*

Date/time of re-extubation __ __ /__ __ /__ __ __ __ *dd/mm/yyyy* __ __ : __ __ *(24 hour clock)* Re-extubation N/A* ☐ **Patient died*

SECTION 3: READMISSIONS TO ANY WARDS (before hospital discharge)

Date/time of re-admission to CICU/HDU __ __ /__ __ /__ __ __ __ *dd/mm/yyyy* __ __ : __ __ *(24 hour clock)*

Date/time of re-admission to ward __ __ /__ __ /__ __ __ __ *dd/mm/yyyy* __ __ : __ __ *(24 hour clock)*

Date/time of re-admission to CICU/HDU __ __ /__ __ /__ __ __ __ *dd/mm/yyyy* __ __ : __ __ *(24 hour clock)*

Date/time of re-admission to ward __ __ /__ __ /__ __ __ __ *dd/mm/yyyy* __ __ : __ __ *(24 hour clock)*

SECTION 4: OTHER COMPLICATIONS RE-OCCURRENCE

Complete this section for re-occurrence of any post-operative complications, using the relevant code from the list given.

Code	Date started *(dd/mm/yyyy)*:	SAE* Yes	SAE* No
☐	__ __ /__ __ /__ __ __ __	☐	☐
☐	__ __ /__ __ /__ __ __ __	☐	☐
☐	__ __ /__ __ /__ __ __ __	☐	☐
☐	__ __ /__ __ /__ __ __ __	☐	☐
☐	__ __ /__ __ /__ __ __ __	☐	☐

COMPLICATION CODES:

A=TIA,
B=pancreatitis,
C=intestinal obstruction/perforation,
D=other GI complication,
E=post-op haemorrhage,
F=ARDS,
G=tracheostomy,
H=initiation of CPAP,
I=pneumothorax requiring chest drainage,
J=pleural effusion requiring drainage,
K=other pulmonary complication,
L=SVT/AF requiring treatment,
M=VF/VT requiring intervention,
N=pacing,
O=other arrhythmia,
P=DVT,
Q=pulmonary embolus,
R=Other thromboembolic complication
S=low cardiac output requiring management,
T=wound dehiscence

*Tick SAE as Yes for any complications listed that met the definition of serious, i.e. are/were life-threatening, resulted in persistent or significant disability/incapacity, prolonged hospitalisation or resulted in death.

Name of person completing form* (capitals) _____ Signature of person completing form _____ Date completed *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

Name of person entering data* (capitals) _____ Date data entered *(dd/mm/yyyy)* __ __ /__ __ /__ __ __ __

** Names must appear on the site signature & delegation log*