RE02: Confirmation of Eligibility and Randomization Form Version: A

SECTION A: GENERAL INFORMATION				
A1. Subject ID				
A2. Date of Eligibility Determination				
SECTION B: TRUST SCORE				
This form is to be completed for all consented p surgery.	patients prior to	Parameter	Finding	Points
B1. Date of Birth		age of the patient in years	<= 65 years	0
			> 65 years	1
B2. Gender	Male	Gender	male	0
	© Female		female	1
B3. Hemoglobin (g/dL)		hemoglobin	>= 13.5 g/dL	0
20(g, a2)		nemoglobin	< 13.5 g/dL	1
			< 13.5 g/dL	
B4. Weight (kg)		body weight in kilograms	>=77 kilograms	0
			< 77 kilograms	1
B5. Elective Surgery	O Yes O No	elective surgery	yes	0
			no (nonelective)	1
B6. Serum Creatinine (mg/dL)		serum creatinine	<= 1.36 mg/dL (120 µmol/L)	0
			> 1.36 mg/dL (120 µmol/L)	1
B7. Does the subject have a history of cardiac surgery?	O Yes O No	history of previous cardiac surgery	no	0
			yes	1
B8. Surgical Task	Solution Solution	surgical task	isolated	0
	(single procedure)  Non-		nonisolated (CABG + valve replacement, etc)	1
	Isolated			
B9. TRUST Score				
SECTION C: BLOOD TYPE				
C1. ABO Blood Group	O A			
	<b>©</b> В			
	O AB			

C2. Rh Type	O Positive Negative
SECTION D: INCLUSION CRITERIA	
D1. Is subject scheduled for complex cardiac surgery with planned use of median sternotomy and cardio-pulmonary bypass?	○ Yes ○ No (Ineligible)
SECTION E: EXCLUSION CRITERIA	
E1. Did the subject refuse blood products?	C Yes (Ineligible) C No
E2. Is the subject having minimally invasive surgery?	○ Yes (Ineligible) ○ No
E3. Does the subject have a known transfusion reaction history?	C Yes (Ineligible) C No
E4. Does the subject have known red blood cell antibodies requiring antigen negative units?	○ Yes (Ineligible) ○ No
E5. Does the subject require washed products, volume reduced products, or products with additive solution removed?	C Yes (Ineligible) C No
E6. Is the subject expected to have residual cyanosis with oxygenation saturation < 90?	C Yes (Ineligible) C No
E7. Is the subject expected to have a left ventricular assist device (LVAD) or extra corporeal membrane oxygenation (ECMO) support pre-operatively or planned need post-operatively?	○ Yes (Ineligible) ○ No
E8. Is the subject expected to experience cardiogenic shock that would require an Intra-aortic balloon pump (IABP)? (IABP done for unstable angina or prophylactically for low ejection fraction is not excluded).	C Yes (Ineligible) C No
E9. Does the subject have a planned Deep Hypothermic Circulatory Arrest (DHCA)?	C Yes (Ineligible) C No
E10. Does the subject have renal dysfunction requiring renal replacement therapies (hemodialysis (HD), continuous venovenous hemofiltration (CVVH)) pre-operatively?	C Yes (Ineligible) C No
E11. Is the use of a heparin alternative planned for this subject, e.g., bivalirudin?	Tes (mengible) = No
E12. Is the use of autologous or directed donations planned for this subject?	Yes (Ineligible) No
E13. Has the subject received a RBC transfusion during the hospitalization for the study-qualifying surgery?	C Yes (Ineligible) C No
E14. Has the subject been randomized into the RECESS study previously?	○ Yes (Ineligible) ○ No
SECTION F: ELIGIBILITY DETERMINATION	
F1. Is the subject eligible to be randomized into the RECESS Study?	○ Yes ○ No
SECTION G: RANDOMIZATION AND STRATIFICA	TION
G1. Is the subject currently in the ICU at the time of randomization in the RECESS study?	O Yes O No
G2. Has the blood bank verified this subject can be supported with RBC products?	Yes No
a. Please select which units of blood the blood bank is unable to provide for this subject	<ul> <li>Red Blood Cell units stored ≤ 10 days</li> <li>RBC stored units ≥ 21 days</li> <li>Both Red Blood Cell units stored ≤ 10 days</li> <li>AND ≥ 21 days</li> </ul>
b. Were more than 6 units requested for this subject?	Yes No
b1. Number of units requested	

RE02: Confirmation of Eligibility and Randomization Form Version: B

SECTION A: GENERAL INFORMATION				
A1. Subject ID				
A2. Date of Eligibility Determination				
A3. Date of Planned Procedure				
SECTION B: TRUST SCORE				
This form is to be completed for all consented p surgery.	atients prior to	Parameter	Finding	Points
B1. Date of Birth		age of the patient in	<= 65 years	0
		years	> 65 years	1
B2. Gender	Male	Gender	male	0
	Female		female	1
P3 Hamaslahin (a/dl.)				
B3. Hemoglobin (g/dL)		hemoglobin	>= 13.5 g/dL	0
			< 13.5 g/dL	1
B4. Weight (kg)		body weight in kilograms	>=77 kilograms	0
			< 77 kilograms	1
B5. Elective Surgery	C Yes C No	elective surgery	yes	0
			no (nonelective)	1
B6. Serum Creatinine (mg/dL)		serum creatinine	<= 1.36 mg/dL (120 µmol/L)	0
			> 1.36 mg/dL (120 µmol/L)	1
B7. Does the subject have a history of cardiac surgery?	O Yes O No	history of previous cardiac surgery	no	0
			yes	1
B8. Surgical Task	○ Isolated	surgical task	isolated	0
	(single procedure)  Non-	-	non-isolated (CABG + valve replacement, etc)	1
	Isolated			
B9. Minimum TRUST Score				
SECTION C: BLOOD TYPE				
C1. ABO Blood Group	O A			
	O B			

	C AB
	0 0
C2. Rh Type	○ Positive ○ Negative
SECTION D: INCLUSION CRITERIA	
D1. Is subject scheduled for complex cardiac surgery with planned use of median sternotomy with or without cardio-pulmonary bypass?	C Yes C No (Ineligible)
SECTION E: EXCLUSION CRITERIA	
E1. Did the subject refuse blood products?	C Yes (Ineligible) C No
E2. Is the subject having minimally invasive surgery?	○ Yes (Ineligible) ○ No
E3. Does the subject have a known transfusion reaction history?	C Yes (Ineligible) C No
E4. Does the subject have known red blood cell antibodies requiring antigen negative units?	O Yes (Ineligible) O No
E5. Does the subject require washed products, volume reduced products, or products with additive solution removed?	C Yes (Ineligible) C No
E6. Is the subject expected to have residual cyanosis with oxygenation saturation < 90?	O Yes (Ineligible) O No
E7. Is the subject expected to have a left ventricular assist device (LVAD) or extra corporeal membrane oxygenation (ECMO) support pre-operatively or planned need post-operatively?	○ Yes (Ineligible) ○ No
E8. Is the subject expected to experience cardiogenic shock that would require an Intra-aortic balloon pump (IABP)? (IABP done for unstable angina or prophylactically for low ejection fraction is not excluded).	C Yes (Ineligible) C No
E9. Does the subject have a planned Deep Hypothermic Circulatory Arrest (DHCA)?	O Yes (Ineligible) O No
E10. Does the subject have renal dysfunction requiring renal replacement therapies (hemodialysis (HD), continuous venovenous hemofiltration (CVVH)) pre-operatively?	C Yes (Ineligible) C No
E11. Is the use of a heparin alternative planned for this subject, e.g., bivalirudin?	○ Yes (Ineligible) ○ No
E12. Is the use of autologous or directed donations planned for this subject?	○ Yes (Ineligible) ○ No
E13. Has the subject received a RBC transfusion during the hospitalization for the study-qualifying surgery?	C Yes (Ineligible) C No
E14. Has the subject been randomized into the RECESS study previously?	Yes (Ineligible) No
SECTION F: ELIGIBILITY DETERMINATION	
F1. Is the subject eligible based on inclusion/exclusion criteria?	○ Yes ○ No
SECTION G: RANDOMIZATION AND STRATIFICA	TION
G1. Is the subject currently in the ICU at the time of randomization in the RECESS study?	○ Yes ○ No
G2. How many crossmatched units have been reque	ested for this subject?
G3. a. Date Transfusion Service contacted for RBC u	nit availability
b. Time Transfusion Service contacted for RBC u	nit availability

G4. Has the blood bank verified enough suitable units stored less than or equal to 10 days AND stored greater or equal to 21 days are present

No in the current inventory to meet the crossmatch request? a. Please select which units of blood the blood Red Blood Cell units bank is unable to provide for this subject stored ≤ 10 days RBC stored units ≥ 21 days Both Red Blood Cell units stored ≤ 10 days AND ≥ 21 days DONE

RE02: Confirmation of Eligibility and Randomization Form Version: C

SECTION A: GENERAL INFORMATION				
A1. Subject ID		1		
A2. Date of Eligibility Determination				
A3. Date of Planned Procedure				
	,			
SECTION B: TRUST SCORE				
This form is to be completed for all consented to surgery.	patients prior	Parameter	Finding	Points
B1. Date of Birth		age of the patient in years	<= 65 years	0
			> 65 years	1
B2. Gender	O Male	Gender	male	0
	© Female		female	1
			I	
B3. Hemoglobin (g/dL)		hemoglobin	>= 13.5 g/dL	0
			< 13.5 g/dL	1
B4. Weight (kg)		body weight in kilograms	>=77 kilograms	0
			< 77 kilograms	1
B5. Elective Surgery	C Yes C No	elective surgery	yes	0
			no (nonelective)	1
B6. Serum Creatinine (mg/dL)		serum creatinine	<= 1.36 mg/dL (120 µmol/L)	0
			> 1.36 mg/dL (120 µmol/L)	1
B7. Does the subject have a history of cardiac surgery?	C Yes C No	history of previous cardiac surgery	no	0
			yes	1
B8. Surgical Task	Solution Isolated	surgical task	isolated	0
	(single procedure)  Non-		non-isolated (CABG + valve replacement, etc)	1
	Isolated			
B9. Minimum TRUST Score				
SECTION C: BLOOD TYPE				
C1. ABO Blood Group	О A О В			

	O AB
	O 0
C2. Rh Type	C Positive C Negative
•	o rositive o negative
SECTION D: INCLUSION CRITERIA	
D1. Is subject scheduled for complex cardiac	C Vac C Na (Inclinible)
surgery with planned use of median sternotomy with or without cardio-pulmonary bypass?	○ Yes ○ No (Ineligible)
SECTION E: EXCLUSION CRITERIA	
E1. Did the subject refuse blood products?	C Yes (Ineligible) C No
E2. Is the subject having minimally invasive surgery?	○ Yes (Ineligible) ○ No
E3. Does the subject have a known transfusion reaction history?	C Yes (Ineligible) C No
E4. Does the subject require washed products, volume reduced products, or products with additive solution removed?	○ Yes (Ineligible) ○ No
E5. Is the subject expected to have residual cyanosis with oxygenation saturation < 90?	O Yes (Ineligible) O No
E6. Is the subject expected to have a left ventricular assist device (LVAD) or extra corporeal membrane oxygenation (ECMO) support pre-operatively or planned need post-operatively?	C Yes (Ineligible) C No
E7. Is the subject expected to experience cardiogenic shock that would require an Intra-aortic balloon pump (IABP)? (IABP done for unstable angina or prophylactically for low ejection fraction is not excluded).	C Yes (Ineligible) C No
E8. Does the subject have a planned Deep Hypothermic Circulatory Arrest (DHCA)?	○ Yes (Ineligible) ○ No
E9. Does the subject have renal dysfunction requiring renal replacement therapies (hemodialysis (HD), continuous venovenous hemofiltration (CVVH)) pre-operatively?	C Yes (Ineligible) C No
E10. Is the use of a heparin alternative planned for this subject, e.g., bivalirudin?	○ Yes (Ineligible) ○ No
E11. Is the use of autologous or directed donations planned for this subject?	○ Yes (Ineligible) ○ No
E12. Has the subject received a RBC transfusion during the hospitalization for the study-qualifying surgery?	C Yes (Ineligible) C No
E13. Has the subject been randomized into the RECESS study previously?	O Yes (Ineligible) O No
SECTION F: ELIGIBILITY DETERMINATION	
F1. Is the subject eligible based on inclusion/exclusion criteria?	O Yes O No
SECTION G: RANDOMIZATION AND STRATIFICA	TION
G1. Is the subject currently in the ICU at the time of randomization in the RECESS study?	C Yes C No
G2. How many crossmatched units have been reque	ested for this
subject? G3. a. Date Transfusion Service contacted for RBC u	unit availability
b. Time Transfusion Service contacted for RBC u	unit availability
G4. Has the blood bank verified enough suitable un or equal to 10 days AND stored greater or equa present in the current inventory to meet the cro	al to 21 days are

a. Please select which units of blood the blood bank is unable to provide for this subject

C Red Blood Cell units stored ≤ 10 days
 C RBC stored units ≥ 21 days
 C Both Red Blood Cell units stored ≤ 10 days AND ≥ 21 days

# Transfusion Medicine/Hemostasis Clinical Trials Network RE04: Demographics and Medical History Form Version: A

SECTION A: GENERAL INFORMATION						
A1.	Subject ID					
SEC	TION B: DEMOGRAPHICS					
B1.		<ul><li>Hispanic or La</li><li>Not Hispanic</li><li>Refused</li><li>Not Obtained</li></ul>	or Latino			
B2.	Race	Yes	No	Refused	Not Obtained/ Unknown	
	a. Native American	0	0	0	0	
	<b>b.</b> Asian	0	O	0	О	
	<b>c.</b> Black, African origin/African American	0	0	0	С	
	d. Hawaiian or Pacific Islander	0	0	0	С	
	e. White	0	0	0	0	
	f. Other	0	0	0	0	
	f1. Other, specify					
вз.	Height (cm)					
	TION C: MEDICAL HISTORY					
C1.	Does the subject currently carry a diagnosis of hypertension?	○ Yes ○ No (C	(2)			
	a. Currently treated?	○ Yes ○ No				
C2.	Does the subject currently carry a diagnosis of diabetes?	○ Yes ○ No (C	23)			
	a. Treatment	Oral agent Insulin Behavorial				
СЗ.	Does the subject have a history of smoking?	C Yes C No (C	24)			
	<b>a.</b> Is the subject a current smoker? (within the last 30 days)	○ Yes ○ No				

	<b>b.</b> Cigarette pack years	
C4.	Does the subject have a known history of Chronic Obstructive Pulmonary Disease (COPD)?	○ Yes ○ No
C5.	Does the subject have a known history of Myocardial Infarction?	○ Yes ○ No
C6.	Does the subject have a known history of Congestive Heart Failure?	○ Yes ○ No
С7.	Does the subject have a known history of stroke/Transient Ischemic Attack?	○ Yes ○ No
C8.	Has the subject had previous vascular surgery?	○ Yes ○ No
C9.	Has the subject ever had a red blood cell transfusion?	C Yes C No (C10) C Unknown (C10)
	<b>a.</b> Date of most recent transfusion prior to this admission	
	<b>b.</b> Was the subject ever transfused at this institution?	○ Yes ○ No (C10)
	<b>b1.</b> Date of most recent transfusion at this institution	
Ente	r the most recent left ventricular ejection frac	tion prior to date of surgery, or during surgery but prior to CPB.
C10.	. Date of left ventricular ejection fraction assessment	
	<b>a.</b> Time of left ventricular ejection fraction assessment	
C11.	. Was a numeric value obtained for the left ventricular ejection fraction?	C Yes C No (C11b)
	a. Left ventricular ejection fraction (%)	
	<b>b.</b> Left ventricular ejection fraction (category)	O Normal
		Moderately depressed
		<ul><li>Severly depressed</li><li>Other</li></ul>
		J 5.1.3.
DON	IE .	

RE05: Adverse Event Checklist Version: A

SEC	TION A: GENERAL INFORMATION	
A1.	Subject ID	
A2.	Date of Assessment	
	·	
	TION B: CLINICAL EVENTS	
B1.	Did the subject experience any of the following events on the assessment date?	O Yes O No (END)
B2.	Myocardial Infarction Event/Cardiac ischemia: Grade 2: Asymptomatic and cardiac enzymes minimally abnormal and no evidence of ischemic ECG changes	○ Yes ○ No
	Grade 3: Severe symptoms; cardiac enzymes abnormal; hemodynamically stable; ECG changes consistent with infarction	
	Grade 4: Life-threatening consequences;hemodynamically unstable	
В3.	Pulmonary Embolism: a blockage of an artery in the lungs by fat, air, a blood clot, or tumor cells	○ Yes ○ No
B4.	<b>Stroke Event:</b> characterized by sudden loss of sensory function due to an intracranial vascular event	○ Yes ○ No
B5.	Renal Event includes any of the following: bladder spasms, cystitis, fistula, incontinence, leak, obstruction, perforation, prolapse of stoma, renal failure, stricture/stenosis, electrolyte wasting, urinary frequency/urgency, urinary retention, or urine color change	○ Yes ○ No
В6.	Infection/Sepsis Event defined as: Grade 2: localized, local intervention indicated	C Yes C No
	Grade 3: IV antibiotic, antifungal, or antiviral intervention indicated; interventional radiology or operative intervention indicated	
	Grade 4: Life-threatening consequences (e.g., septic shock, hypotension, acidosis, necrosis)	
В7.	<b>Ventricular tachycardia:</b> characterized by a dysrhythmia with a heart rate greater then 100 beats per minute that originates distal to the bundle of His	○ Yes ○ No
B8.	Ventricular fibrillation:     characterized by a dysrhythmia without discernible QRS     complexes due to rapid repetitive excitation of myocardial fibers     without coordinated contraction of the ventricles	○ Yes ○ No
B9.	TACO (Transfusion-associated congestive heart failure/transfusion-associated circulatory overload): characterized by increased blood pressure, tachycardia, setting of rapid or massive transfusion, and a positive fluid balance	○ Yes ○ No
B10	TRALI (Transfusion-related acute lung injury): characterized by acute respiratory distress, hypoxemia, fever, and hypotension; bilateral pulmonary edema involving the entire lung fields; recent transfusion of plasma-containing blood components; and a normal or low pulmonary wedge pressure	C Yes C No
B11	<ul> <li>Anaphylaxis: characterized by a rapid onset of hypotension (often severe) and dypsnea; erythematous confluent rash; and no evidence of</li> </ul>	○ Yes ○ No

pulmona	ry edema		
function	ost Disease: rized by an erythematous rash, diarrhea, and liver test abnormalities. Fever may or may not be present. aplasia and pancytopenia may also occur	○ Yes ○ No	
Do not report e	vents listed below (B13-B29) separately if reported	as part of one of the events listed above.	
B13. <b>Allergic Re</b> characte exposure	raction: rized by an adverse local or general response from e to an allergen	C Yes C No	
Grade 2:	Intervention or infusion interruption indicated; responds promptly to symptomatic treatment; prophylactic medications indicated for <= 24 hours		
Grade 3:	Prolonged; recurrence of symptoms following initial improvement; hospitalization indicated for clinical sequelae		
Grade 4:	Life-threatening consequences; urgent intervention indicated.		
	lycardia: rized by a dysrhythmia with a heart rate less then 60 r minute that originates in the sinus node	○ Yes ○ No	
Grade 2:	symptomatic, medical intervention indicated		
Grade 3:	severe, medically significant, medical intervention indicated		
Grade 4:	life-threatening consequences; urgent intervention indicated		
	ycardia: rized by a dysrhythmia with a heart rate greater then s per minute that originates in the sinus node	○ Yes ○ No	
Grade 2:	symptomatic, non-urgent medical intervention indicated		
Grade 3:	urgent medical intervention indicated		
	ion: rized by pathological increase in blood pressure; a I elevation in the blood pressure exceeding 140/90	○ Yes ○ No	
	on: rized by a blood pressure that is below the normal I for an individual in a given environment	O Yes O No	
Grade 2:	<u> </u>		
Grade 3:	Medical intervention or hospitalization indicated		
Grade 4:	Life threatening and urgent intervention indicated		
B18. <b>Dyspnea:</b> characte breathin	rized by an uncomfortable sensation of difficulty g	○ Yes ○ No	
Grade 2:	shortness of breath with minimal exertion; limiting instrumental ADL		
Grade 3:	shortness of breath at rest; limiting self care ADL		

○ Yes ○ No

Grade 4: life-threatening consequences; urgent intervention

B19. Hypoxia: characterized by a decrease in the level of oxygen in the body

> Grade 2: Decreased oxygen saturation with exercise (e.g., pulse oximeter <88%); intermittent supplemental oxygen

Grade 3: Decreased oxygen saturation at rest (e.g., pulse oximeter <88% or PaO2 <=55mmHg)

Grade 4: life-threatening airway compromise; urgent intervention indicated (e.g., tracheotomy or intubation)

B20. Wheezing:

characterized by a high-pitched, whistling sound during breathing. It results from the narrowing or obstruction of the respiratory airways

Grade 2: Moderate symptoms; medical intervention

Grade 3: Severe respiratory symptoms limiting self care ADL; oxygen therapy or hospitalization indicated Grade 4: Life-threatening consequences; urgent intervention indicated
intervention indicated
B21. Cough:
characterized by sudden, often repetitive, spasmodic contraction of the thoracic cavity, resulting in violent release of air from the lungs and usually accompanied by a distinctive sound
Grade 2: Moderate symptoms, medical intervention indicated; limiting instrumental ADL
Grade 3: Severe symptoms; limiting self care ADL
B22. <b>Fever:</b> characterized by elevation of the body's temperature above the upper limit of normal
Grade 2: >39.0 - 40.0 degrees C (>102.3 - 104.0 degrees F)
Grade 3: >40.0 degrees C (>104.0 degrees F) for <24 hours
Grade 4: >40.0 degrees C (>104.0 degrees F) for >24 hours
characterized by a sensation of cold that often marks a physiologic response to sweating after a fever
Grade 2: moderate tremor of the entire body; narcotics indicated
Grade 3: Severe or prolonged, not responsive to narcotics
B24. <b>Hemolysis:</b>
characterized by laboratory test result that indicates widespread erythrocyte cell membrane destruction
Grade 2: Evidence of hemolysis and ≥ 2 gm decrease in hemoglobin, no transfusion
Grade 3: Transfusion or other medical intervention indicated (e.g., steroids)
Grade 4: Life-threatening consequences; urgent intervention indicated
B25. <b>Hyperkalemia:</b> High serum potassium  O Yes O No
Grade 2: > 5.5 - 6.0 mmol/L
Grade 3: > 6.0 - 7.0 mmol/L; hospitalization indicated
Grade 4: > 7.0 mmol/L; life-threatening consequences
B26. <b>Hyperphosphatemia:</b> abnormally high levels of phosphate in the blood
B27. <b>Hypocalcemia:</b> Low serum calcium  O Yes O No
Grade 2: < 8.0 - 7.0 mg/dL; < 2.0 - 1.75 mmol/L Ionized calcium < 1.0 - 0.9 mmol/L; symptomatic
Grade 3: < 7.0 - 6.0 mg/dL; < 1.75 - 1.5 mmol/L Ionized calcium < 0.9 - 0.8 mmol/L; hospitalization indicated
Grade 4: < 6.0 mg/dL; < 1.5 mmol/L Ionized calcium < 0.8 mmol/L; life-threatening consequences
B28. <b>Hyperbilirubinemia:</b> low serum bilirubin
Grade 2: >1.5 - 3.0 x ULN
Grade 3: >3.0 - 10.0 x ULN
Grade 4: >10.0 x ULN
B29. Hemoglobinuria:
DZ3, HEIIIUUIUUIIII.
characterized by laboratory test results that indicate the presence of free hemoglobin in the urine.
characterized by laboratory test results that indicate the presence



Tempo	rary Save
Save	Reload

		RE07: Pre-Op Measurements Form Version: A		Save Reload
SEC	TION A. CENEDAL INFORMATION			
	TION A: GENERAL INFORMATION			
	Subject ID			
A2. I	Date of planned surgery			
SEC	TION B: LABORATORY DATA			
Reco	rd the measurement closest to the day of surg	ery		
D1	Lab	Result	Date Drawn	Time Drawn
B1.	Creatinine	mg/dL		
B2.	Bilirubin	mg/dL		
В3.	Platelet Count	x 10^9 L		
B4.	Hemoglobin	g/L		
B5.	Fibrinogen	mg/dL		
B6.	BUN	mg/dL		
B7.	ALT (SGPT)	U/L		
B8.	Troponin I	ng/mL		
SEC	TION C: HEMODYNAMIC PARAMETERS			
Reco	ord the measurement closest to the day of surg	ery		
C1.	Heart rate a. Result (beats per minute)			
	b. Date Obtained			
	c. Time Obtained			
C2.	Blood pressure a1. Systolic Blood Pressure (mmHg)			
	a2. Diastolic Blood Pressure (mmHg)			
	b. Date Obtained			
	c. Time Obtained			
C3.	Arterial oxygen saturation (SaO <sub>2</sub> )			
	a. Result (%) b. Date Obtained			
	c. Time Obtained			
C4.	Systemic oxygen saturation (Pulse Oximeter R	desult, SpO <sub>2</sub> )		
	a. Result (%)			
	b. Date Obtained			
	c. Time Obtained			
C5.	Venous oxygen saturation $(PO_2 \text{ venous, SvO}_2)$ a. Result (%)			
	b. Date Obtained			
	c. Time Obtained			
C6.	Glascow coma score			
	a1. Eye Opening Result	C 4 = Spontaneous eye opening C 3 = Eye opening to verbal stimuli		
		C 2 = Eye opening to pain C 1 = No Response		

a2. Best Verbal Response	
az. best verbai kesponse	C 5 = Subject is oriented and converses
	C 4 = Subject is disoriented and converses C 3 = Subject uses inappropriate words
	C 2 = Subject makes incomprehensible sounds
	C 1 = No response
a3. Best Motor Response	C 6 = Subject obeys command
	C 5 = Subject localizes pain
	C 4 = Subject has flexion withdrawal
	C 3 = Subject has abnormal flexion (decorticate rigidity) C 2 = Subject has extension (decerebrate rigidity)
	C 1 = No response
a4. Total Score	
b. Date Obtained	
c. Time Obtained	
C7. Is the subject currently receiving oxygen?	C Yes C No (C8a)
a. Oxygen device	C Nasal cannula
	© Mask
	C Intubated
b. Liters of oxygen received	
c. FiO2 (%)	
d. Date Obtained	
e. Time Obtained	
C8. PO <sub>2</sub> Arterial (PaO <sub>2</sub> , Oxygen level)	
a. Result (mmHg)	
b. Date Obtained	
c. Time Obtained	
C9. Does the subject have a central venous	C Yes C No (C11)
catheter in place?	
C10. Central Venous Pressure (CVP)  a. Result (cm of water)	
b. Date Obtained	
c. Time Obtained	
C11. Does the subject have a pulmonary	C Yes C No (C21 or C22)
artery/Swan-Ganz catheter in place? C12. Systemic Vascular Resistance (SVR)	
a. Result (dynes)	
b. Date Obtained	
c. Time Obtained	
C13. Pulmonary Capillary Wedge Pressure (PCW	P)
a. Result (mm Hg)	
b. Date Obtained	
c. Time Obtained	
C14. Cardiac output	
a. Result (L/m)	
b. Date Obtained	
c. Time Obtained	
C15. Cardiac index	
a. Result (L/min/m²)	
b. Date Obtained	
c. Time Obtained	
C16. Oxygen consumption as reported on machine	e/readout
a. Result (L/min)	
b. Date Obtained	
c. Time Obtained	
Components of oxygen consumption calculation: Must be done within 30 minutes of one another.	
C17. Arterial oxygen saturation (SaO <sub>2</sub> )	
a. Result (%)	
b. Date Obtained	
c. Time Obtained	

C18. Venous oxygen saturation (SvO <sub>2</sub> )			
a. Result (%)			
b. Date Obtained			
c. Time Obtained			
C19. Cardiac output a. Result (L/min)			
b. Date Obtained			
c. Time Obtained			
C20. Mean Artery Pressure a. Result (mmHg)			
b. Date Obtained			
c. Time Obtained			
C21. Did the subject have an arterial blood ga drawn per standard of care?	S C Yes C No (D1)		
C22.Whole blood lactic acid a. Result (mmol/L)			
b. Date Drawn			
c. Time Drawn			
SECTION D: PRE-OP MEDICATIONS  D1. Did the subject receive any of the following	C Ves C Ne (FND)		
medications in the 7 days prior to surgery of the surgery date before bypass?	r on Yes O No (END)		
		Yes	No
a.	Abiciximab (ReoPro)	0	0
b.	Aprotinin (Trasylol)	0	0
c.	Argatroban	0	0
d.	Aspirin	0	0
e.	Bivalirudin (Angiomax)	0	0
f.	Cilostazol (Pletal)	0	0
g.	Clopidogrel (Plavix)	0	0
h.	Dabigatran	0	0
i.	Desirudin	0	0
j.	Desmopressin (DDAVP, Stimate, Minirin)	0	0
k.	Direct Thrombin Inhibitors	0	0
I.	Epsilon Aminocaproic Acid (Amicar)	0	0
m.	Eptifibatide (Integrilin)	0	0
n.	Factor VIIa (NovoSeven)	0	0
p.	Heparin (unfractionated)	0	0
0.	Heparin (low molecular)	0	0
q.	Hirudin	0	0
г.	Lepirudin	0	0
S.	Melagatran	0	0

0

0

0

0

0

0

Nitric Oxide Gas

Prasugrel (Effient)

Sildenafil (Viagra)

w.

Prothrombin Complex Concentrates

x.	Steroids	0	0
y.	Ticlopidine (Ticlid)	0	0
z.	Tirofiban (Aggrestat)	0	0
aa.	Tranexamic Acid (Cyklokapron)	0	0
bb.	Warfarin (Coumadin)	0	0
ZZ.	Other anticoagulant or antiplatelet	0	О
	zz1. Specify other		
			4
			▽
DONE			



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#### Form RE07 – Pre-Op Measurements Worksheet

C1. Heart Rate (beats per minute)			planned surgery	/	_ / (mm/dd/yyyy)		
Section B: LABORATORY D	ATA	Record the measure	ment closest to	the day of surgery			
Lab	Result	Date Drawn (mm/dd/y	yyy) Time D	awn (24 hour clock)			
B1. Creatinine (mg/dL)		///		:			
B2. Bilirubin (mg/dL)		//		:			
B3. Platelet Count (x10 <sup>9</sup> L)		//		:			
B4. Hemoglobin (g/L)		///		:			
B5. Fibrinogen (mg/dL)		///		:			
B6. BUN (mg/dL)		///		:			
B7. ALT (SGPT) (U/L)		//		:			
B8. Troponin-I (ng/ml)		//		:			
Section C: HEMODYNAMIC F	PARAMETERS	Record the measure	ement closest to	the day of surgery			
Parameter				a. Result	b. Date Obta	ained	c. Time Obtained
C1. Heart Rate (beats per min	nute)		Not done		/	_/	::
C2. Blood Pressure (mmHg)			Not done	/	/	_/	::
C3. Arterial Oxygen Saturation	n (SaO <sub>2</sub> ) (%)		Not done		/	_/	::
C4. Systemic Oxygen Saturation	on (Pulse Oximet	er Result, SpO <sub>2</sub> ) (%)	Not done		/	_/	::
C5. Venous Oxygen Saturation	n (PO <sub>2</sub> venous, S	vO <sub>2</sub> ) (%)	Not done		/	_/	::
C6. Glasgow Coma Score			Not done				
a1. Eye opening result	4 = Sponta	aneous eye opening	3 = Eye ope	ning to verbal stimuli	2 = Eye opening to pa	ain	☐ 1 = No response
a2. Best verbal response	•	et is oriented and convel et uses inappropriate wo		<ul><li>Subject is disoriente</li><li>Subject makes incor</li></ul>		☐ 1 = No	response
a3. Best motor response	3 = Subject	t obeys command thas abnormal flexion ticate rigidity)		= Subject localizes pair = Subject has extensio	n n (decerebrate rigidity)	☐ 4 = Sub	oject has flexion withdrawal Response

			b. Date Obtained	c. Time Obtained
a4. Total Score			//	:
C7. Is the subject currently receiving oxygen?	□₁ Yes	☐ <sub>2</sub> No <b>(C8a)</b>		
a. Oxygen device □₁ Nasal cannula	□ <sub>2</sub> Mask	☐ <sub>3</sub> Intubated	b. Liters of oxygen received	
		c. Result	d. Date Obtained	e. Time Obtained
	FiO2 (%)		//	:
Parameter		a. Result	b. Date Obtained	c. Time Obtained
C8. PO <sub>2</sub> Arterial (PaO <sub>2</sub> , Oxygen level) (mmHg)	Not done		//	:
C9. Does the subject have a central venous catheter in place?	□₁ Yes	□ <sub>2</sub> No		
Parameter		a. Result	b. Date Obtained	c. Time Obtained
C10. Central Venous Pressure (CVP) (mmHg)	$\square_{-1}$ Not done		//	:
C11. Does the subject have a pulmonary artery/Swan-Ganz catheter in	n place?	□ <sub>1</sub> Yes □ <sub>2</sub> No <b>(C22)</b>		
Parameter		a. Result	b. Date Obtained	c. Time Obtained
C12. Systemic Vascular Resistance (SVR) (dynes)	Not done		//	:
C13. Pulmonary Capillary Wedge Pressure (PCWP) (mmHg)	Not done		///	:
C14. Cardiac Output (L/min)	Not done		///	:
C15. Cardiac Index (L/min/m²)	Not done		//	::
C16. Oxygen Consumption as reported on machine/readout (L/min)	Not done		//	::
Components of oxygen consumption calculation: Must be done w	vithin 30 minutes	s of each other.		
Parameter		a. Result	b. Date Obtained	c. Time Obtained
C17. Arterial Oxygen Saturation (SaO2) (%)	Not done		/	:
C18. Venous oxygen saturation (SvO <sub>2</sub> ) (%)	Not done		/	:

C7. Is the subject currently receiving oxygen?		☐ <sub>2</sub> No <b>(C8a)</b>		
a. Oxygen device □₁ Nasal cannula	$\square_2$ Mask	□ <sub>3</sub> Intubated	b. Liters of oxygen received	
		c. Result	d. Date Obtained	e. Time Obtained
	FiO2 (%)		//	:
Parameter		a. Result	b. Date Obtained	c. Time Obtained
C8. PO <sub>2</sub> Arterial (PaO <sub>2</sub> , Oxygen level) (mmHg)	$\square_{-1}$ Not done		///	:
C9. Does the subject have a central venous catheter in place?	□₁ Yes	$\square_2$ No		
Parameter		a. Result	b. Date Obtained	c. Time Obtained
C10. Central Venous Pressure (CVP) (mmHg)	Not done		///	:
C11. Does the subject have a pulmonary artery/Swan-Ganz catheter	in place?	□₁ Yes □₂ No (C2	22)	
Parameter		a. Result	b. Date Obtained	c. Time Obtained
C12. Systemic Vascular Resistance (SVR) (dynes)	Not done		///	:
C13. Pulmonary Capillary Wedge Pressure (PCWP) (mmHg)	Not done		///	<u>-</u>
C14. Cardiac Output (L/min)	Not done		///	:
C15. Cardiac Index (L/min/m²)	☐ <sub>-1</sub> Not done		///	::
C16. Oxygen Consumption as reported on machine/readout (L/min)	Not done		///	::
Components of oxygen consumption calculation: Must be done	within 30 minute			
Parameter		a. Result	b. Date Obtained	c. Time Obtained
C17. Arterial Oxygen Saturation (SaO2) (%)	Not done		///	:
C18. Venous oxygen saturation (SvO <sub>2</sub> ) (%)	Not done		//	:
C19. Cardiac Output (L/min)	Not done		///	:
C20. Mean Artery Pressure (mmHg)	Not done		/	:
C21. Did the subject have an arterial blood gas drawn per standard of	of care?	□ <sub>1</sub> Yes □ <sub>2</sub> No		
Parameter		a. Result	b. Date Obtained	c. Time Obtained
C22. Whole Blood Lactic Acid (mmol/L)	Not done		///	·
d. Source of Blood	☐	2 Peripheral	$\square_3$ Free Flowing Venous Ca	atheter

_		_	_
<b>-</b>	 		 

Section	D: PRE-OP MEDICATIONS					
	I the subject receive any of the following medi bass or onset of procedure?	□₁ Yes	□ <sub>2</sub> No <b>(END)</b>			
a.	Abiciximab (ReoPro)	□₁ Yes	$\square_2$ No	p. Therapeutic Heparin (low molecular)	□₁ Yes	$\square_2$ No
b.	Aprotinin (Trasylol)	□₁ Yes	$\square_2$ No	q. Hirudin	□₁ Yes	$\square_2$ No
C.	Argatroban	□₁ Yes	$\square_2$ No	r. Lepirudin	□₁ Yes	$\square_2$ No
d.	Aspirin	□₁ Yes	$\square_2$ No	s. Melagatran	□₁ Yes	$\square_2$ No
e.	Bivalirudin (Angiomax)	□₁ Yes	$\square_2$ No	t. Nitric Oxide Gas	□₁ Yes	□ <sub>2</sub> No
f.	Cilostazol (Pletal)	□₁ Yes	$\square_2$ No	u. Prasugrel (Effient)	□₁ Yes	□ <sub>2</sub> No
g.	Clopidogrel (Plavix)	□₁ Yes	$\square_2$ No	v. Prothrombin Complex Concentrates	□₁ Yes	□ <sub>2</sub> No
h.	Dabigatran	□₁ Yes	$\square_2$ No	w. Sildenafil (Viagra)	□₁ Yes	□ <sub>2</sub> No
i.	Desirudin	□₁ Yes	$\square_2$ No	x. Steroids	□₁ Yes	$\square_2$ No
j.	Desmopressin (DDAVP, Stimate, Minirin)	□₁ Yes	$\square_2$ No	y. Ticlopidine (Ticlid)	□₁ Yes	□ <sub>2</sub> No
k.	Direct Thrombin Inhibitors	□₁ Yes	$\square_2$ No	z. Tirofiban (Aggrestat)	□₁ Yes	$\square_2$ No
l.	Epsilon Aminocaproic Acid (Amicar)	□₁ Yes	$\square_2$ No	aa. Tranexamic Acid (Cyklokapron)	□₁ Yes	□ <sub>2</sub> No
m.	Eptifibatide (Integrilin)	□₁ Yes	$\square_2$ No	bb. Warfarin (Coumadin)	□₁ Yes	$\square_2$ No
n.	Factor VIIa (NovoSeven)	□₁ Yes	$\square_2$ No	zz. Other anticoagulant or antiplatelet	□₁ Yes	$\square_2$ No
0.	Therapeutic Heparin (unfractionated)	□₁ Yes	$\square_2$ No	Specify other:		_



TMH - 08: RECESS

#### Form RE07 – Pre-Op Measurements Worksheet

A1. Subject ID:					A2. Da	ate of plar	nned surge	ery//_	(r	mm/dd/yyyy)
Section B: LABORATORY	DATA	Record	the measure	ement closest	to the day of surg	ery				
Lab	a. Result	b. Date D	<b>Drawn</b> (mm/de	d/yyyy) <b>c. T</b>	ime Drawn (24 hot	ur clock)				
B1. Creatinine (mg/dL)		/_	/		:	_				
B2. Bilirubin (mg/dL)		/_	/		:	_				
B3. Platelet Count (x10 <sup>9</sup> L)		/_	/		:	_				
B4. Hemoglobin (g/L)		/_	/		:	_				
B5. Fibrinogen (mg/dL)		/_	/		:	_				
B6. BUN (mg/dL)		/_	/		:	_				
B7. ALT (SGPT) (U/L)		/_	/		:	_				
B8. Troponin-I (ng/ml)		/_	/		:	—				
Section C: Measurements	and Information	Record	the measure	ement closest	to the day of surg	ery				
General Information									п	
C1. Did the subject have an	arterial puncture	or any of the	e following line	es in place in t	he 30 days prior to	surgery?	□₁ Yes	□ <sub>2</sub> No <b>(C2)</b>		
C1a. Pulmonary Artery li catheter	ne/Swan-Ganz	□₁ Yes	□ <sub>2</sub> No	C1c. Centra	al venous catheter	□₁ Yes	□ <sub>2</sub> No	C1e. Arterial puncture	□₁ Yes	□ <sub>2</sub> No
C1b. Arterial line		□₁ Yes	□ <sub>2</sub> No	C1d. PICC	line	□₁ Yes	□ <sub>2</sub> No			
C2. Did the subject receive s	supplemental oxyg	gen in the 3	0 days prior to	surgery?	□ <sub>1</sub> Yes □ <sub>2</sub> N	lo <b>(C3)</b>				
C2a. Oxygen device	□₁ Nas	sal cannula		<sub>2</sub> Mask	☐ <sub>3</sub> Intuba	ated				
C2b. Liters of oxygen red	ceived:									
C3. This question intentio	nally left blank									
Other MODS Measurement	ts				a. Result		b.	Date Obtained	c. Time C	Obtained
C4. Heart Rate (beats per m	ninute)			Not done	e			/	:-	
C5. Blood Pressure (mmHg)				Not done	e	/		/	:	<u> </u>
C6. PO <sub>2</sub> Arterial (PaO <sub>2</sub> , Oxyg	gen level) (mmHg	)		Not done	9			/	:	
C7. FiO <sub>2</sub> (%)				Not done	e			//	:_	

Other MODS Measurements of	continued:		a. Result	b. Date Obta	ained	c. Time Obtained
C8. Mean Arterial Pressure (mr	mHg)	□ <sub>-1</sub> Not done		/	_/	:
C9. Central Venous Pressure (	(CVP) (mmHg)	Not done		/	_/	i
C10. Glasgow Coma Score		Not done				
a1. Eye opening result	4 = Spontaneous eye opening	☐ 3 = Eye op	ening to verbal stimuli	2 = Eye opening to pa	ain 🗌	1 = No response
a2. Best verbal response	☐ 5 = Subject is oriented and conve ☐ 3 = Subject uses inappropriate w		4 = Subject is disoriente 2 = Subject makes inco		☐ 1 = No res	ponse
a3. Best motor response	☐ 6 = Subject obeys command ☐ 3 = Subject has abnormal flexion (decorticate rigidity)		5 = Subject localizes pai 2 = Subject has extensio		☐ 4 = Subject ☐ 1 = No Res	et has flexion withdrawal sponse
a4. Total Glasgow Coma Sc	core:	b. Date Obtair	ned://	c. Time Obt	ained::	' <u></u>
Additional Measurements			a. Result	b. Date Obta	ained	c. Time Obtained
C11. Whole Blood Lactic Acid	(mmol/L)	Not done		/	_/	<b>:_</b>
d. Source of Blood	$\square_1$ Arterial	☐₂ Periphera	l ☐₃ Free Flo	owing Venous Catheter or F	PICC line	
C12. Arterial Oxygen Saturation	n (SaO <sub>2</sub> ) (%)	Not done		/	_/	::
C13. Systemic Oxygen Saturati (%)	ion (Pulse Oximeter Result, SpO <sub>2</sub> )	□ <sub>-1</sub> Not done		/	_/	:
C14. Venous Oxygen Saturatio	n (PO <sub>2</sub> venous, SvO <sub>2</sub> ) (%)	_ <sub>-1</sub> Not done		//	_/	::
C15. Systemic Vascular Resista	ance (SVR) (dynes)	Not done		/	_/	::
C16. Pulmonary Capillary Wed	ge Pressure (PCWP) (mmHg)	Not done		/	_/	::
C17. Cardiac Output (L/min)		Not done		/	_/	:
C18. Cardiac Index (L/min/m²)		Not done		//	_/	
C19. Oxygen Consumption as I	reported on machine/readout (L/min)	Not done		/	_/	<u>:</u>
Components of oxygen cons	umption calculation (Report if no re	adout available	(C19) and done within	30 minutes of each othe	r.)	
C20. Does subject have the 3	components of the oxygen consumptio	n calculation obta	ained within 30 minutes	of each other in 30 days p	rior to surgery?	$\square_1$ Yes $\square_2$ No <b>(D1)</b>
Parameter			a. Result	b. Date Obt	ained	c. Time Obtained
C21. Arterial Oxygen Saturation	n (SaO2) (%)	□ <sub>-1</sub> Not done		/	_/	:
C22. Venous oxygen saturation	n (SvO <sub>2</sub> ) (%)	_ <sub>-1</sub> Not done		//	_/	:
C23. Cardiac Output (L/min)		Not done		/	_/	:

-		-	-	1

Section D: PRE-OP MEDICATIONS						
	D1. Did the subject receive any of the following medications in the 7 days prior to surgery or on the surgery date but prior to bypass or onset of procedure?					□ <sub>2</sub> No <b>(END)</b>
a.	Abiciximab (ReoPro)	□₁ Yes	$\square_2$ No	p. Therapeutic Heparin (low molecular)	□₁ Yes	$\square_2$ No
b.	Aprotinin (Trasylol)	□₁ Yes	$\square_2$ No	q. Hirudin	□₁ Yes	$\square_2$ No
C.	Argatroban	□₁ Yes	$\square_2$ No	r. Lepirudin	□₁ Yes	$\square_2$ No
d.	Aspirin	□₁ Yes	$\square_2$ No	s. Melagatran	□₁ Yes	$\square_2$ No
e.	Bivalirudin (Angiomax)	□₁ Yes	$\square_2$ No	t. Nitric Oxide Gas	□₁ Yes	$\square_2$ No
f.	Cilostazol (Pletal)	□₁ Yes	$\square_2$ No	u. Prasugrel (Effient)	□₁ Yes	$\square_2$ No
g.	Clopidogrel (Plavix)	□₁ Yes	$\square_2$ No	v. Prothrombin Complex Concentrates	□₁ Yes	$\square_2$ No
h.	Dabigatran	□₁ Yes	$\square_2$ No	w. Sildenafil (Viagra)	□₁ Yes	$\square_2$ No
i.	Desirudin	□₁ Yes	$\square_2$ No	x. Steroids	□₁ Yes	$\square_2$ No
j.	Desmopressin (DDAVP, Stimate, Minirin)	□₁ Yes	$\square_2$ No	y. Ticlopidine (Ticlid)	□₁ Yes	$\square_2$ No
k.	Direct Thrombin Inhibitors	□₁ Yes	$\square_2$ No	z. Tirofiban (Aggrestat)	□₁ Yes	$\square_2$ No
l.	Epsilon Aminocaproic Acid (Amicar)	□₁ Yes	$\square_2$ No	aa. Tranexamic Acid (Cyklokapron)	□₁ Yes	$\square_2$ No
m.	Eptifibatide (Integrilin)	□₁ Yes	$\square_2$ No	bb. Warfarin (Coumadin)	□₁ Yes	$\square_2$ No
n.	Factor VIIa (NovoSeven)	□₁ Yes	$\square_2$ No	zz. Other anticoagulant or antiplatelet	□₁ Yes	$\square_2$ No
0.	Therapeutic Heparin (unfractionated)	□₁ Yes	$\square_2$ No	Specify other:		_

#### Transfusion Medicine/Hemostasis Clinical Trials Network RE07: Pre-Op Measurements Form SECTION A: GENERAL INFORMATION **Temporary Save** A1. Subject ID Save Reload A2. Date of planned surgery SECTION B: LABORATORY DATA Record the measurement closest to the start time of surgery Date Drawn Time Drawn B1. Creatinine mg/dL B2. Bilirubin mg/dL B3. Platelet Count x 10^9 L B4. Hemoglobin a/L B5. Fibrinogen mg/dL B6. BUN mg/dL B7. ALT (SGPT) U/L SECTION C: MEASUREMENTS AND INFORMATION Record the measurement closest to the start time of surgery <u>General Information:</u> Did the subject have an arterial puncture or any of the following lines in place in the 30 days prior to surgery? C Yes C No (C2) Pulmonary Artery line/Swan-Ganz catheter a. O Yes O No Arterial line b. O Yes O No Central venous catheter O Yes O No PICC line d. O Yes O No Arterial Puncture e. O Yes O No Did the subject receive supplemental oxygen C2. O Yes O No (C4a) entering the OR? Oxygen device a. Nasal cannula Mask O Intubated b. Liters of oxygen received C3. This question intentionally left blank Other MODS Measurements: C4. Heart Rate Result (beats per minute) a. Date Obtained Time Obtained C. C5. Blood Pressure a1. Systolic Blood Pressure (mmHg) a2. Diastolic Blood Pressure (mmHg) Date Obtained b. Time Obtained C6. PO<sub>2</sub> Arterial (PaO<sub>2</sub>, Oxygen level) a. Result (mmHg) Date Obtained b. Time Obtained C. C7. FiO<sub>2</sub>

Result (%)

b. Date Obtained	
c. Time Obtained	
C8. Mean Arterial Pressure	
a. Result (mmHg)	
b. Date Obtained	
c. Time Obtained	
C9. Central Venous Pressure (CVP)	
a. Result (mmHg)	
b. Date Obtained	
c. Time Obtained	
10. Glasgow Coma Score	
a1. Eye Opening Result	C Spontaneous eye opening C Eye opening to verbal stimuli
	C Eye opening to pain
a2. Best Verbal Response	C No Response
az. best verbai kesponse	C Subject is oriented and converses C Subject is disoriented and converses
	C Subject uses inappropriate words
	C Subject makes incomprehensible sounds C No response
a3. Best Motor Response	C Subject obeys command
	C Subject localizes pain
	C Subject has flexion withdrawal C Subject has abnormal flexion (decorticate rigidity)
	C Subject has extension (decerebrate rigidity)
a4. Total Score	C No response
b. Date Obtained	* See note below
c. Time Obtained	
* All subjects that are sedated during the performing of	false CCC programment abouted ability to the
the observed scores reported for the individual componsassessment of the subject, but the overall score must below rather than the sum of the individual component.  Code 88 = Sedated, Expected to Be Normal: he by history before surgery and no catastrophic evaluation but currently unable to assess because of sedated. Not Normal: neurologic fur (prior stroke, tumor or trauma sequelae, cognitive intra-operative history, but currently unable to a	be given one of the specific special codes scores.  ad normal neurologic function for age rents to change that status are clinically evident, ion. rection not normal by pre-operative history rely challenged, behavioral disorder, etc.) or
<u>Additional Measurements:</u> C11. Whole Blood Lactic Acid	
a. Result (mmol/L)	
b. Date Drawn	
c. Time Drawn	
d. Source of blood	C Arterial
	C Peripheral
C12. Arterial Oxygen Saturation (SaO <sub>2</sub> )	C Free Flowing Venous Catheter or PICC line
a. Result (%)	
b. Date Obtained	
c. Time Obtained	
C13. Systemic Oxygen Saturation (Pulse Oximeter R	esult, SpO <sub>2</sub> )
a. Result (%)	
b. Date Obtained	
c. Time Obtained	
SECTION D: PRE-OP MEDICATIONS  D1. Did the subject receive any of the following	V. C. N. (SND)
medications in the 7 days prior to surgery or on the surgery date but prior to bypass or onset	Yes C No (END)
of procedure?	
a. Abicixi	Mab (ReoPro)
ABIGIA	

b.	Aprotinin (Trasylol)	0	0	
c.	Argatroban	0	0	
d.	Aspirin	0	0	
е.	Bivalirudin (Angiomax)	0	0	
f.	Cilostazol (Pletal)	0	0	
g.	Clopidogrel (Plavix)	0	0	
h.	Dabigatran	0	0	
i.	Desirudin	0	0	
j.	Desmopressin (DDAVP, Stimate, Minirin)	0	0	
k.	Direct Thrombin Inhibitors	0	0	
I.	Epsilon Aminocaproic Acid (Amicar)	0	0	
m.	Eptifibatide (Integrilin)	0	0	
n.	Factor VIIa (NovoSeven)	0	O	
0.	Therapeutic heparin (unfractionated)	0	0	
p.	Therapuetic heparin (low molecular)	0	0	
q.	Hirudin	0	0	
r.	Lepirudin	0	0	
s.	Melagatran	0	0	
t.	Nitric Oxide Gas	0	0	
u.	Prasugrel (Effient)	0	0	
v.	Prothrombin Complex Concentrates	0	0	
w.	Sildenafil (Viagra)	0	0	
x.	Steroids	0	0	
y.	Ticlopidine (Ticlid)	0	0	
z.	Tirofiban (Aggrestat)	0	0	
aa.	Tranexamic Acid (Cyklokapron)	0	0	
bb.	Warfarin (Coumadin)	0	0	
zz.	Other anticoagulant or antiplatelet	0	0	
	zz1. Specify other			
			_	
			~	

RE08: Procedure Data Form

	V 61 51611 / N
SECTION A: GENERAL INFORMATION	
A1. Subject ID	
SECTION B: TYPE OF PROCEDURE	all that apply
Indicate the type of procedure(s) preformed. Select B1. Surgical access	© Primary median sternotomy
G .	Repeat median sternotomy
	C Thoracotomy
	Other (minimally invasive)
a. Specify other	A
	<del>-</del>
	v
B2. Coronary Surgery	C Yes C No
a. Simple Coronary: Single Graft	C Yes C No
b. Complex Coronary	C Yes C No
b1. Coronary Distal Graft	○ Yes ○ No
b1a. Number of distal grafts	
b2. Anomalous origin repair	C Yes C No
b3. Fistulae repair	O Yes O No
B3. Valve Surgery	O Yes O No
a. Aortic Valve Surgery	C Yes C No
a1. Replacement	O Yes O No
a2. Repair/Reconstruction	O Yes O No
a3. Reconstruction with Conduit	O Yes O No
a4. Conduit replacement	C Yes C No
b. Mitral Valve Surgery	C Yes C No
b1. Annuloplasty only	C Yes C No
b2. Replacement	C Yes C No
b3. Reconstruction	C Yes C No
c. Pulmonary Valve Surgery	C Yes C No
c1. Annuloplasty Only	C Yes C No
c2. Replacement	C Yes C No
c3. Reconstruction	C Yes C No
c4. Valvectomy	C Yes C No
c5. Conduit placement	C Yes C No
c6. Conduit replacement	C Yes C No
d. Tricuspid Valve Surgery	C Yes C No

d1. Annuloplasty Only	© Yes © No
d2. Replacement	C Yes C No
d3. Reconstruction	○ Yes ○ No
d4. Valvectomy	○ Yes ○ No
B4. Septal Repair	O Yes O No
a. Atrial Septal Defect	○ Yes ○ No
b. Ventricular Septal Defect	○ Yes ○ No
c. Patent Foramen Ovale Closure	○ Yes ○ No
B5. Ventricular Surgery	○ Yes ○ No
a1. Aneurysm repair	○ Yes ○ No
a2. Batista	○ Yes ○ No
a3. Ventricular repair	○ Yes ○ No
a4. Septation	○ Yes ○ No
a5. Miscellaneous conduit to Aorta	○ Yes ○ No
a6. Double Outlet Left Ventricle Repair	○ Yes ○ No
a7. Double Outlet Right Ventricle Repair	○ Yes ○ No
B6. Great Vessel Surgery	○ Yes ○ No
a. Aorta	○ Yes ○ No
a1. Coarctation repair	○ Yes ○ No
a2. Interruption repair	C Yes C No
a3. Arch repair	O Yes O No
a4. Ross	C Yes C No
a5. Kono	C Yes C No
b. Pulmonary Artery	C Yes C No
b1. Main Pulmonary Artery Stenosis	C Yes C No
b2. Branch stenosis	C Yes C No
c. Pulmonary Veins	C Yes C No
c1. Total Anomalous Pulmonary Venous Return	C Yes C No
c2. Partial Anomalous Pulmonary Venous Return	O Yes O No
d. Partial Ductus Arteriosus	C Yes C No
B7. Complex Congenital Surgery	C Yes C No
a1. Transposition Great Arteries	C Yes C No
a2. Hypoplastic Left Heart Syndrome	○ Yes ○ No
a3. Tetrology of Fallot	C Yes C No
a4. Coronary Triatriatum	○ Yes ○ No
a5. Atrioventricular Canal	O Yes O No
a6. Truncus Arteriosus	○ Yes ○ No
b. Palliative	O Yes O No
b1. Shunt: Systemic to Pulmonary	○ Yes ○ No
b2. Shunt ligation and takedown	○ Yes ○ No
b3. Pulmonary Artery banding	○ Yes ○ No
b4. Pulmonary Artery debanding	○ Yes ○ No
b5. Damus-Kaye-Stanzel	O Yes O No
b6. Unidirectional Glenn	C Yes C No

b7. Bidirectional Glenn	C Yes C No			
b8. Bilateral bidirectional Glenn	○ Yes ○ No			
b9. Hemi-Fontan	O Yes O No			
b10. Single ventricle (Fontan)	C Yes C No			
B8. Other cardiac surgery/procedure	O Yes O No			
a. Specify surgery/procedure	<u> </u>			
	~			
SECTION C: PROCEDURE DATA				
C1. Date entered operating room				
C2. Time entered operating room				
C3. Date exited operating room				
C4. Time exited operating room				
C5. Was the procedure done off pump?	C Yes C No			
a. Type of pump used	C Centrifugal Pump			
	Roller Pump			
C6. CBP duration (minutes)				
C7. Duration of aortic cross clamp (minutes)				
C8. Was cell saver used during the procedure?	O Yes O No			
a. Volume of cell saver blood administered (mL)				
C9. Number of Acute Normovolemic Hemodilution uni collected	ts			
a. Number of Acute Normovolemic Hemodilution units administered				
C10. Was a balloon pump inserted in the Operating Room?	○ Yes ○ No			
C11. Lowest core temperature (degrees Celsius)				
SECTION D: INTRAOPERATIVE MEDICATIONS				
D1. Did the subject receive any of the following medications intraoperatively?	C Yes C No			
D1. Did the subject receive any of the following	C Yes C No	Yes	No	
D1. Did the subject receive any of the following medications intraoperatively?	O Yes O No Abiciximab (ReoPro)	Yes	No O	
D1. Did the subject receive any of the following medications intraoperatively?  a.				
D1. Did the subject receive any of the following medications intraoperatively?  a.  b.	Abiciximab (ReoPro)	0	0	
D1. Did the subject receive any of the following medications intraoperatively?  a. b.	Abiciximab (ReoPro) Aprotinin (Trasylol)	0	0	

f.	Cilostazol (Pletal)	0	0	
g.	Clopidogrel (Plavix)	0	0	
h.	Dabigatran	0	0	
í.	Desirudin	0	0	
j.	Desmopressin (DDAVP, Stimate, Minirin)	0	0	
k.	Direct Thrombin Inhibitors	0	0	
I.	Epsilon Aminocaproic Acid (Amicar)	0	0	
m.	Eptifibatide (Integrilin)	0	0	
n.	Factor VIIa (NovoSeven)	0	0	
p.	Heparin (unfractionated)	0	0	
0.	Heparin (low molecular)	0	0	
q.	Hirudin	0	0	
r.	Lepirudin	0	0	
S.	Melagatran	0	0	
t.	Nitric Oxide Gas	0	0	
u.	Prasugrel (Effient)	0	0	
v.	Prothrombin Complex Concentrates	0	0	
w.	Sildenafil (Viagra)	0	0	
x.	Steroids	0	0	
y.	Ticlopidine (Ticlid)	0	0	
z.	Tirofiban (Aggrestat)	0	0	
aa.	Tranexamic Acid (Cyklokapron)	0	0	
bb.	Warfarin (Coumadin)	0	0	
zz.	Other anticoagulant or antiplatelet	0	0	
	1. Specify other			

RE08: Procedure Data Form  Version: B						
SECTION A: GENERAL INFORMATION	SECTION A: GENERAL INFORMATION					
A1. Subject ID						
SECTION B: TYPE OF PROCEDURE						
Indicate the type of procedure(s) preformed	Select all that apply.					
B1. Surgical access	<ul><li>Primary median sternotomy</li><li>Repeat median sternotomy</li><li>Thoracotomy</li><li>Other (minimally invasive)</li></ul>					
a. Specify other						
B2. Coronary Surgery						
a. Simple Coronary: Single Graft	○ Yes ○ No					
b. Complex Coronary	○ Yes ○ No (B3)					
b1. Coronary Distal Graft	○ Yes ○ No					
b1a. Number of distal grafts						
b2. Anomalous origin repair	○ Yes ○ No					
b3. Fistulae repair	○ Yes ○ No					
B3. Valve Surgery	○ Yes ○ No (B4)					
a. Aortic Valve Surgery	○ Yes ○ No (B3b)					
a1. Replacement	O Yes O No					
a2. Repair/Reconstruction	○ Yes ○ No					
a3. Reconstruction with Conduit	O Yes O No					
a4. Conduit replacement	○ Yes ○ No					
b. Mitral Valve Surgery	○ Yes ○ No (B3c)					
b1. Annuloplasty only	○ Yes ○ No					
b2. Replacement	O Yes O No					
b3. Reconstruction	○ Yes ○ No					
c. Pulmonary Valve Surgery	O Yes O No (B3d)					
c1. Annuloplasty Only	○ Yes ○ No					
c2. Replacement	O Yes O No					
c3. Reconstruction	○ Yes ○ No					
c4. Valvectomy	O Yes O No					
c5. Conduit placement	○ Yes ○ No					
c6. Conduit replacement	O Yes O No					
d. Tricuspid Valve Surgery	○ Yes ○ No (B4)					

4 4 1 1 2 2	
d1. Annuloplasty Only	O Yes O No
d2. Replacement	○ Yes ○ No
d3. Reconstruction	○ Yes ○ No
d4. Valvectomy	○ Yes ○ No
B4. Septal Repair	○ Yes ○ No (B5)
a. Atrial Septal Defect	○ Yes ○ No
b. Ventricular Septal Defect	O Yes O No
c. Patent Foramen Ovale Closure	○ Yes ○ No
B5. Ventricular Surgery	O Yes O No (B6)
a1. Aneurysm repair	○ Yes ○ No
a2. Batista	C Yes C No
a3. Ventricular repair	○ Yes ○ No
a4. Septation	C Yes C No
a5. Miscellaneous conduit to Aorta	○ Yes ○ No
a6. Double Outlet Left Ventricle Repair	○ Yes ○ No
a7. Double Outlet Right Ventricle Repair	○ Yes ○ No
B6. Great Vessel Surgery	○ Yes ○ No (B7)
a. Aorta	○ Yes ○ No (B6b)
a1. Coarctation repair	○ Yes ○ No
a2. Interruption repair	○ Yes ○ No
a3. Arch repair	○ Yes ○ No
a4. Ross	○ Yes ○ No
a5. Kono	○ Yes ○ No
b. Pulmonary Artery	○ Yes ○ No (B6c)
b1. Main Pulmonary Artery Stenosis	○ Yes ○ No
b2. Branch stenosis	○ Yes ○ No
c. Pulmonary Veins	O Yes O No
c1. Total Anomalous Pulmonary Venous Return	○ Yes ○ No
c2. Partial Anomalous Pulmonary Venous Return	O Yes O No
d. Partial Ductus Arteriosus	○ Yes ○ No
B7. Complex Congenital Surgery	○ Yes ○ No (B8)
a1. Transposition Great Arteries	○ Yes ○ No
a2. Hypoplastic Left Heart Syndrome	O Yes O No
a3. Tetrology of Fallot	○ Yes ○ No
a4. Coronary Triatriatum	○ Yes ○ No
a5. Atrioventricular Canal	○ Yes ○ No
a6. Truncus Arteriosus	C Yes C No
b. Palliative	○ Yes ○ No (B8)
b1. Shunt: Systemic to Pulmonary	C Yes C No
b2. Shunt ligation and takedown	C Yes C No
b3. Pulmonary Artery banding	○ Yes ○ No
b4. Pulmonary Artery debanding	C Yes C No
b5. Damus-Kaye-Stanzel	○ Yes ○ No
b6. Unidirectional Glenn	○ Yes ○ No

b7. Bidirectional Glenn	O Yes O No			
b8. Bilateral bidirectional Glenn	○ Yes ○ No			
b9. Hemi-Fontan	○ Yes ○ No			
b10. Single ventricle (Fontan)	○ Yes ○ No			
B8. Other cardiac surgery/procedure	○ Yes ○ No (C1)			
a. Specify surgery/procedure				
	<u> </u>			
SECTION C: PROCEDURE DATA				
C1. Date entered operating room				
C2. Time entered operating room				
C3. Date exited operating room				
C4. Time exited operating room				
C5. Was the procedure done on cardio-pulmonary bypass?	O Yes O No (C7)			
a. Type of pump used	<ul><li>Centrifugal Pump</li><li>Roller Pump</li></ul>			
C6. CBP duration (minutes)				
C7. Duration of aortic cross clamp (minutes)				
C8. Was cell saver used during the procedure?	C Yes C No (C9)			
a. Volume of cell saver blood administered (mL)				
C9. Number of Acute Normovolemic Hemodilution unicollected	(If ANH units were not coll	ected en	ter -1)	
a. Number of Acute Normovolemic Hemodilution units administered				
C10. Was a balloon pump inserted in the Operating Room?	○ Yes ○ No			
C11. Lowest core temperature (degrees Celsius)				
SECTION D: INTRAOPERATIVE MEDICATIONS				
D1. Did the subject receive any of the following medications intraoperatively?	C Yes C No (END)			
		Yes	No	
a.	Abiciximab (ReoPro)	0	0	
b.	Aprotinin (Trasylol)	0	0	
c.	Argatroban	0	0	
d.	Aspirin	0	0	
e.	Bivalirudin (Angiomax)	0	0	

f.	Cilostazol (Pletal)	0	0	
g.	Clopidogrel (Plavix)	0	0	
h.	Dabigatran	0	0	
i.	Desirudin	0	0	
j.	Desmopressin (DDAVP, Stimate, Minirin)	0	0	
k.	Direct Thrombin Inhibitors	0	0	
1.	Epsilon Aminocaproic Acid (Amicar)	0	0	
m.	Eptifibatide (Integrilin)	0	0	
n.	Factor VIIa (NovoSeven)	0	0	
0.	Heparin (unfractionated)	0	0	
p.	Heparin (low molecular)	0	0	
q.	Hirudin	0	0	
r.	Lepirudin	0	0	
s.	Melagatran	0	0	
t.	Nitric Oxide Gas	0	0	
u.	Prasugrel (Effient)	0	0	
v.	Prothrombin Complex Concentrates	0	0	
w.	Sildenafil (Viagra)	0	0	
x.	Steroids	0	0	
y.	Ticlopidine (Ticlid)	0	0	
z.	Tirofiban (Aggrestat)	0	0	
aa.	Tranexamic Acid (Cyklokapron)	0	0	
bb.	Warfarin (Coumadin)	0	0	
ZZ.	Other anticoagulant or antiplatelet	0	0	
	1. Specify other			
				≠
				_

DONE

RE09: Post-Op/Daily Measurement Form

Tempo	rary Save
Save Reload	

			Version:	A	
_					
SEC	TION A: GENE	ERAL INFORMATION			
A1.	Subject ID				
A2.	Assessment D	ate			
SEC	TION B: LABO	DRATORY RESULTS			
Reco	ord the measu	rement closest to 7:00 AM. Note	e: If the Assessment Date is Day 0, record	d the measurement closes	t to 7:00 AM but AFTER the end time of surgery.
	Lab		Result	Time Drawn	
B1.	Creatinine	(mg/dL)			
B2.	Bilirubin	(mg/dL)			
В3	Platelet Count	(x 10^9 L)			
B4.	Hemoglobin	(g/L)			
B5.	Fibrinogen	(mg/dL)			
B6.	BUN	(mg/dL)			
B7.	ALT (SGPT)	(U/L)			
B8.	Troponin	(ng/mL)			
		ODYNAMIC PARAMETERS			
		rement closest to 7:00 AM. Note	e: If the Assessment Date is Day 0, record	d the measurement closes	t to 7:00 AM but AFTER the end time of surgery.
C1.	Heart rate a. Result (be	ats per minute)			
	b. Time Obta				
C2.	Blood pressur	re			
	a1. Systolic	Blood Pressure (mmHg)			
	a2. Diastolio	c Blood Pressure (mmHg)			
	b. Time Obta	ined			
C3.		en saturation (SaO <sub>2</sub> )			
	a. Result (%) b. Time Obta				
C4		gen saturation (Pulse Oximeter	Pecult SpO )		
04.	a. Result (%)		Kesuit, 5po <sub>2</sub> )		
	b. Time Obta	ined			
C5.	Venous oxyge	en saturation (PO <sub>2</sub> venous, SvO	2)		
	a. Result (%)				
	b. Time Obta	ined			
C6.	Glascow Com	a Score ening Result			
	ат. Еуе Оре	eriirig Kesuit	<ul><li>4 = Spontaneous eye opening</li><li>3 = Eye opening to verbal stimuli</li></ul>		
			C 2 = Eye opening to pain C 1 = No Response		
	a2. Best Ve	rbal Response	5 = Subject is oriented and converse	es	
			<ul> <li>4 = Subject is disoriented and conve</li> </ul>	erses	
			3 =Subject uses inappropriate word		
			2 = Subject makes incomprehensible	e sounds	
	93 Doot M	ntar Pasnansa	1 = No response		
	as. best MC	otor Response	<ul><li>6 = Subject obeys command</li><li>5 = Subject localizes pain</li></ul>		
			6 4 =Subject has flexion withdrawal		
				corticate rigidity)	
			C 2 = Subject has extension (decerebra	ate rigidity)	
			↑ 1 =No response		

a-	4. Total Score			
b. '	Time Obtained			
C7. Is	the subject currently receiving oxygen?	O Yes O	No (C8a)	
а.	Oxygen device	O Nasal ca		
		O Mask		
h	Liters of oxygen received	O Intubat	ed	
	FiO2 (%)			
	Time Obtained			
-	Arterial (PaO <sub>2</sub> , Oxygen level)			
a. I	Result (mmHg)			
b. '	Time Obtained			
C9. Do	pes the subject have a central venous theter in place?	O Yes O	No (C11)	
	entral Venous Pressure (CVP)			
a. I	Result (cm of water)			
b. '	Time Obtained			
C11. Do	pes the subject have a pulmonary	O Yes O	No(C21or	(22)
art	tery/Swan-Ganz catheter in place?	S 103 S	140(02101	JZZ)
	rstemic Vascular Resistance (SVR)  Result (dynes)			
	Time Obtained			
	ılmonary Capillary Wedge Pressure (PCWP Result (mm Hg)	)		
	Time Obtained			
	rdiac output Result (L/m)			
	Time Obtained			
	rdiac index Result (L/min per square meter)			
	Time Obtained			
	aygen consumption as reported on machine.  Result (L/min)	/readout		
	Time Obtained			
of one a	nents of oxygen consumption calculation: Manother.	ust be done	within 30	minutes
C17 Art	terial oxygen saturation (SaO <sub>2</sub> )			
	result (%)			
	ime Obtained			
	enous oxygen saturation (SvO <sub>2</sub> )			
	result (%)			
b. Ti	ime Obtained			
	ardiac output			
	esult (L/min)			
b. Ti	ime Obtained			
	ean Artery Pressure			
a. I	Result (mmHg)			
b. '	Time Obtained			
	d the subject have an arterial blood gas	O Yes O	No (D1)	
	awn per standard of care? hole blood lactic acid		. ,	
	Result (mmol/L)			
	Time Drawn			
SECTIO	ON D: MEDICATION CHECKLIST			
D1. Plea	ase indicate if the subject received any of following medications on the date of	O Yes O N	No (END)	
	essment.			
	Abiainingh (Dagba)		Yes No	
	Abiciximab (ReoPro)		0 0	
b. /	Aprotinin (Trasylol)		0 0	

C.	Argatroban	0	
d.	Aspirin	0	
e.	Bivalirudin (Angiomax)	0	Ī
f.	Cilostazol(Pletal)	0	T
g.	Clopidogrel (Plavix)	0	Ť
h.	Dabigatran	0	T
i.	Desirudin	0	Ť
j.	Desmopressin (DDAVP, Stimate, Minirin)	0	Ť
k.	Direct Thrombin Inhibitors	0	Ť
I.	Epsilon Aminocaproic Acid (Amicar)	0	Ť
m.	Eptifibatide (Integrilin)	0	Ť
n.	Factor VIIa (NovoSeven)	0	Ť
p.	Heparin (unfractionated)	0	Ť
Ο.	Heparin (low molecular)	0	Ť
q.	Hirudin	0	Ť
r.	Lepirudin	0	t
S.	Melagatran	0	Ť
t.	Nitric Oxide Gas	0	Ť
u.	Prasugrel (Effient)	0	Ť
V.	Prothrombin Complex Concentrates	0	Ť
w.	Sildenafil (Viagra)	0	Ť
х.	Steroids	0	Ť
у.	Ticlopidine (Ticlid)	0	Ť
Z.	Tirofiban (Aggrestat)	0	Ť
аа.	Tranexamic Acid (Cyklokapron)	0	Ť
bb.	Warfarin (Coumadin)	0	Ť
ZZ.	Other anticoagulant or antiplatelet	0	Ť
	zz1. Specify other		

RE09: Post-Op/Daily Measurement Form

Tempo	rary Save
Save	Reload

			Version:	С	
SEC	TION A: GENE	ERAL INFORMATION			
A1.	Subject ID				
A2.	Assessment D	ate			
SEC	TION B: LABO	DRATORY RESULTS			
Reco	rd the measu	rement closest to 7:00 AM. Note	: If the Assessment Date is Day 0, record	I the measurement closes	t to 7:00 AM but AFTER the end time of surgery.
D1	Lab		Result	Time Drawn	
	Creatinine	(mg/dL)			
	Bilirubin	(mg/dL)			
В3	Platelet Count	(x 10^9 L)			
B4.	Hemoglobin	(g/L)			
B5.	Fibrinogen	(mg/dL)			
В6.	BUN	(mg/dL)			
B7.	ALT (SGPT)	(U/L)			
B8.	Troponin-I	(ng/mL)			
Ш					
SEC	TION C: HEMO	ODYNAMIC PARAMETERS			
Reco	rd the measu	rement closest to 7:00 AM. Note	: If the Assessment Date is Day 0, record	I the measurement closes	t to 7:00 AM but AFTER the end time of surgery.
C1.	Heart rate	ats per minute)			
	b. Time Obta				
C2	Blood pressur				
C2.		Blood Pressure (mmHg)			
	a2. Diastolio	Blood Pressure (mmHg)			
	b. Time Obta	ined			
СЗ.	Arterial oxyge	en saturation (SaO <sub>2</sub> )			
	a. Result (%)	1			
	b. Time Obta	ined			
C4.	Systemic oxy	gen saturation (Pulse Oximeter	Result, SpO <sub>2</sub> )		
	a. Result (%)				
	b. Time Obta	ined			
C5.		en saturation (PO <sub>2</sub> venous, SvO <sub>2</sub>	)		
	a. Result (%)				
	b. Time Obta				
C6.	a1. Eye Ope	a Score ening Result	C 4 = Spontaneous eye opening		
			O 3 = Eye opening to verbal stimuli		
			<ul><li>2 = Eye opening to pain</li><li>1 = No Response</li></ul>		
	a2. Best Ve	rbal Response	C 5 = Subject is oriented and converse	es	
			C 4 = Subject is disoriented and conve	erses	
			3 = Subject uses inappropriate word	ds	
			C 2 = Subject makes incomprehensible	e sounds	
			C 1 = No response		
	a3. Best Mo	otor Response	6 = Subject obeys command		
			<ul><li>5 = Subject localizes pain</li><li>4 = Subject has flexion withdrawal</li></ul>		
			3 = Subject has abnormal flexion (dec	corticate rigidity)	
			2 = Subject has extension (decerebra		
			C 1 = No response		

a4. Total Score	
b. Time Obtained	
C7. Is the subject currently receiving oxygen?	C Yes C No (C8a)
a. Oxygen device	C Nasal cannula
	C Mask
b. Liters of oxygen received	C Intubated
c. FiO2 (%)	
d. Time Obtained	
C8. PO <sub>2</sub> Arterial (PaO <sub>2</sub> , Oxygen level)  a. Result (mmHg)	
b. Time Obtained	
	C Yes C No
C9. Does the subject have a central venous catheter in place?	Tes O No
C10. Central Venous Pressure (CVP)  a. Result (mmHg)	
b. Time Obtained	
C11. Does the subject have a pulmonary	© Yes © No (C21or C22)
C11. Does the subject have a pulmonary artery/Swan-Ganz catheter in place? C12. Systemic Vascular Resistance (SVR)	5 10 5 No (0220) 022)
a. Result (dynes)	
b. Time Obtained	
C13. Pulmonary Capillary Wedge Pressure (PCWP	)
a. Result (mm Hg)	
b. Time Obtained	
C14. Cardiac output	
a. Result (L/m)	
b. Time Obtained	
C15. Cardiac index a. Result (L/min per square meter)	
b. Time Obtained	
C16. Oxygen consumption as reported on machine	/readout
a. Result (L/min)	, readout
b. Time Obtained	
Components of oxygen consumption calculation: M	ust be done within 30 minutes
of one another.	
C17. Arterial oxygen saturation (SaO <sub>2</sub> )	
a. Result (%)	
b. Time Obtained	
C18. Venous oxygen saturation (SvO <sub>2</sub> )  a. Result (%)	
b. Time Obtained	
C19. Cardiac output	
a. Result (L/min)	
b. Time Obtained	
C20. Mean Artery Pressure	
a. Result (mmHg)	
b. Time Obtained	
C21. Did the subject have an arterial blood gas drawn per standard of care?	C Yes C No (C23)
C22. Whole blood lactic acid	
a. Result (mmol/L)	
b. Time Drawn	
c. Source of blood	C Arterial
	C Peripheral C Free Flowing Venous Catheter
C23. Was the subject on an intra-aortic balloon	C Yes
pump on this day of assessment?	C No
SECTION D: MEDICATION CHECKLIST	

		Yes	No
a.	Abiciximab (ReoPro)	0	0
b.	Aprotinin (Trasylol)	0	0
c.	Argatroban	0	0
d.	Aspirin	0	0
e.	Bivalirudin (Angiomax)	0	0
f.	Cilostazol(Pletal)	0	0
g.	Clopidogrel (Plavix)	0	0
h.	Dabigatran	0	0
i.	Desirudin	0	0
j.	Desmopressin (DDAVP, Stimate, Minirin)	0	0
k.	Direct Thrombin Inhibitors	0	0
I.	Epsilon Aminocaproic Acid (Amicar)	0	0
m.	Eptifibatide (Integrilin)	0	0
n.	Factor VIIa (NovoSeven)	0	0
о.	Heparin (unfractionated)	0	0
p.	Heparin (low molecular)	0	0
q.	Hirudin	0	0
r.	Lepirudin	0	0
s.	Melagatran	0	0
t.	Nitric Oxide Gas	0	0
u.	Prasugrel (Effient)	0	0
٧.	Prothrombin Complex Concentrates	0	0
w.	Sildenafil (Viagra)	0	0
x.	Steroids	0	0
у.	Ticlopidine (Ticlid)	0	0
z.	Tirofiban (Aggrestat)	0	0
aa.	Tranexamic Acid (Cyklokapron)	0	0
bb.	Warfarin (Coumadin)	0	0
zz.	Other anticoagulant or antiplatelet	0	0
	zz1. Specify other		
			<b>A</b>
			7



TMH - 08: RECESS

Study	Day #:	
Juuv	Dav #.	

### Form RE09 – Post-Op Measurements Worksheet

A1. Subject ID:						A2. Da	ate of asso	essment:	//		_ (mm/dd/yy	vyy)
Section B: LABORA	TORY DATA		ord the measu				te: If the A	ssessment	Date is Day 0, reco	ord the	measuren	nent closest
Lab	Result	Time Drav	wn (24 hour clo	ck)	Lab			Re	sult	Time D	)rawn <i>(</i> 2 <i>4</i>	hour clock)
B1. Creatinine (mg/dL)			:		B5. Fibrinoge	n (mg/dL)				_	:	
B2. Bilirubin (mg/dL)			:		B6. BUN (mg	/dL)				_	:	
B3. Platelet Count (x10 <sup>9</sup>	L)		:		B7. ALT (SGI	PT) (U/L)				_	:	
B4. Hemoglobin (g/L)			:		B8. Troponin-	-l (ng/ml)				_	:	
Section C: MEASURE	EMENTS AND INF	ORMATIO			e measureme ent closest to				Assessment Date of surgery.	is Day (	), record t	he
General Information:									(00)			
C1. Did the subject have		lines in place	e or arterial pun	cture	on the assess	sment day?	□ <sub>1</sub> Ye	es □₂ No	(C2)			
C1a. Pulmonary Arte catheter	ry line/Swan-Ganz	□₁ Yes	<del></del> =		Central venou	us catheter	□₁ Yes	□ <sub>2</sub> No	C1e. Arterial pund	cture	□₁ Yes	□ <sub>2</sub> No
C1b. Arterial line		□₁ Yes			PICC line	<u>-</u>	□₁ Yes	□ <sub>2</sub> No				
C2. Did the subject recei	ve supplemental oxy	gen on the a	assessment day	<i>i</i> ?	□ <sub>1</sub> `	Yes □ <sub>2</sub> N	lo (C3)					
C2a. Oxygen device	□ <sub>1</sub> Na	asal cannula	$\square_2$	Masl	k	$\square_3$ Intub	ated					
C2b. Liters of oxyger	received:					<u>-</u>						
C3. Was the subject o	n an intra-aortic ba	illoon pump	on this day o	f ass	sessment?	□₁ Yes	□ <sub>2</sub> No					
Other MODS Measuren	nents:					a. F	Result		b. Time Obtained	I		
C4. Heart Rate (beats p	er minute)		[	N	Not done				:			
C5. Blood Pressure (mn	nHg)		[	N	lot done		_/	_	:			
C6. PO <sub>2</sub> Arterial (PaO2,	Oxygen level) (mm	łg)		N	Not done				:			
C7. FiO <sub>2</sub> (%)			[	N	Not done				:			
C8. Mean Arterial Press	ure (mmHg)		[	N	Not done				:			
C9. Central Venous Pre	ssure (CVP) (mmHg)	)		N	Not done				:			

 	 <b>-</b>		

Other MODS Measurements co	ontinued:						
C10. Glasgow Coma Score		Not done					
a1. Eye opening result	4 = Spontaneous eye opening	3 = Eye oper	ning to verbal stimuli	2 = Eye opening to p	ain 🗌	1 = No resp	onse
a2. Best verbal response	☐ 5 = Subject is oriented and conve ☐ 3 = Subject uses inappropriate wo		= Subject is disoriente ! = Subject makes inco		☐ 1 = No res	sponse	
a3. Best motor response	☐ 6 = Subject obeys command ☐ 3 = Subject has abnormal flexion (decorticate rigidity)		= Subject localizes pai = Subject has extension	n on (decerebrate rigidity)	☐ 4 = Subject ☐ 1 = No Re		n withdrawal
a4. Total Glasgow Coma Sco	re:		b. Time Obtained	:			
Additional Measurements:			a. Resul	t b. Tim	e Obtained		
C11. Whole Blood Lactic Acid (r	mmol/L)	Not done			:		
c. Source of Blood		□₁ Arterial	2 Peripheral	☐ <sub>3</sub> Free F	lowing Venous C	atheter or F	PICC line
C12. Arterial Oxygen Saturation	(SaO <sub>2</sub> ) (%)	Not done			:		
C13. Systemic Oxygen Saturation	n (Pulse Oximeter Result, SpO <sub>2</sub> ) (%)	Not done			<b>:</b>		
C14. Venous Oxygen Saturation	(PO <sub>2</sub> venous, SvO <sub>2</sub> ) (%)	Not done			:		
C15. Systemic Vascular Resistar	nce (SVR) (dynes)	Not done			:		
C16. Pulmonary Capillary Wedge	e Pressure (PCWP) (mmHg)	Not done			<b>:</b>		
C17. Cardiac Output (L/min)		Not done			:		
C18. Cardiac Index (L/min/m²)		Not done			<b>:</b>		
C19. Oxygen Consumption as re	ported on machine/readout (L/min)	Not done			<b>:</b>		
Components of oxygen consu	mption calculation (Report if no rea	dout available (0	C19) and done within	30 minutes of each other	er.)		
C20. Does subject have the 3 co	omponents of the oxygen consumption	calculation obtai	ined within 30 minutes	of each other on the day of	of assessment?	□₁ Yes	☐ <sub>2</sub> No <b>(D1)</b>
Parameter			a. Resul	t b. Tim	ne Obtained		
C21. Arterial Oxygen Saturation	(SaO2) (%)	Not done			:		
C22. Venous oxygen saturation	(SvO <sub>2</sub> ) (%)	Not done			:		
C23. Cardiac Output (L/min)		Not done			:		

_	_	_

Section	Section D: MEDICATION CHECKLIST							
D1. Dic	the subject receive any of the following medicat	ions on the dat	te of assessme	nt?	□₁ Yes	$\square_2$ No <b>(END)</b>		
a.	Abiciximab (ReoPro)	□₁ Yes	$\square_2$ No	p. Therapeutic Heparin (low molecular)	□₁ Yes	□ <sub>2</sub> No		
b.	Aprotinin (Trasylol)	□₁ Yes	$\square_2$ No	q. Hirudin	□₁ Yes	□ <sub>2</sub> No		
C.	Argatroban	□₁ Yes	$\square_2$ No	r. Lepirudin	□₁ Yes	$\square_2$ No		
d.	Aspirin	□₁ Yes	$\square_2$ No	s. Melagatran	□₁ Yes	$\square_2$ No		
e.	Bivalirudin (Angiomax)	□₁ Yes	$\square_2$ No	t. Nitric Oxide Gas	□₁ Yes	$\square_2$ No		
f.	Cilostazol (Pletal)	□₁ Yes	$\square_2$ No	u. Prasugrel (Effient)	□₁ Yes	$\square_2$ No		
g.	Clopidogrel (Plavix)	□₁ Yes	$\square_2$ No	v. Prothrombin Complex Concentrates	□₁ Yes	$\square_2$ No		
h.	Dabigatran	□₁ Yes	$\square_2$ No	w. Sildenafil (Viagra)	□₁ Yes	$\square_2$ No		
i.	Desirudin	□₁ Yes	$\square_2$ No	x. Steroids	□₁ Yes	$\square_2$ No		
j.	Desmopressin (DDAVP, Stimate, Minirin)	□₁ Yes	$\square_2$ No	y. Ticlopidine (Ticlid)	□₁ Yes	$\square_2$ No		
k.	Direct Thrombin Inhibitors	□₁ Yes	$\square_2$ No	z. Tirofiban (Aggrestat)	□₁ Yes	$\square_2$ No		
l.	Epsilon Aminocaproic Acid (Amicar)	□₁ Yes	$\square_2$ No	aa. Tranexamic Acid (Cyklokapron)	□₁ Yes	$\square_2$ No		
m.	Eptifibatide (Integrilin)	□₁ Yes	$\square_2$ No	bb. Warfarin (Coumadin)	□₁ Yes	$\square_2$ No		
n.	Factor VIIa (NovoSeven)	□₁ Yes	$\square_2$ No	zz. Other anticoagulant or antiplatelet	□₁ Yes	$\square_2$ No		
0.	Therapeutic Heparin (unfractionated)	□₁ Yes	$\square_2$ No	Specify other:		_		



TMH - 08: RECESS

Study.	Dav #:	
stuav	Dav #.	

### Form RE09 – Post-Op Measurements Worksheet

A1. Subject ID:	A2. Date of assessment://(mm/dd/yyyy)
	nent closest to 7:00 AM. Note: If the Assessment Date is Day 0, record the measurement closest R the end time of surgery.
Lab Result Time Drawn (24 hour clock)	Lab Result Time Drawn (24 hour clock)
B1. Creatinine (mg/dL) :	B5. Fibrinogen (mg/dL) :
B2. Bilirubin (mg/dL):::	B6. BUN (mg/dL)
B3. Platelet Count (x10 <sup>9</sup> L):::	B7. ALT (SGPT) (U/L):
B4. Hemoglobin (g/L)::::	B8. Troponin-I (ng/ml) Please report the Troponin-I results on the RE24 Form
	the measurement closest to 7:00 AM. Note: If the Assessment Date is Day 0, record the ement closest to 7:00 AM but AFTER the end time of surgery.
C1. Did the subject have any of the following lines in place or arterial punctu	ire on the assessment day? $\square_1$ Yes $\square_2$ No (C2)
C10 Rulmonary Artery line/Swan Conz	c. Central venous catheter $\square_1$ Yes $\square_2$ No C1e. Arterial puncture $\square_1$ Yes $\square_2$ No
C1b. Arterial line ☐₁ Yes ☐₂ No C1	d. PICC line $\square_1$ Yes $\square_2$ No
C2. Did the subject receive supplemental oxygen on the assessment day?	$\square_1 \text{ Yes } \square_2 \text{ No } \textbf{(C3)}$
C2a. Oxygen device $\square_1$ Nasal cannula $\square_2$ Ma	ask □ <sub>3</sub> Intubated
C2b. Liters of oxygen received:	
C3. Was the subject on an intra-aortic balloon pump on this day of a	ssessment?
Other MODS Measurements:	a. Result b. Time Obtained
C4. Heart Rate (beats per minute)	<sub>1</sub> Not done:
C5. Blood Pressure (mmHg)	<sub>1</sub> Not done/:::
C6. PO <sub>2</sub> Arterial (PaO2, Oxygen level) (mmHg)	<sub>1</sub> Not done:::
C7. FiO <sub>2</sub> (%)	<sub>1</sub> Not done:::
C8. Mean Arterial Pressure (mmHg)	<sub>1</sub> Not done: ::
C9. Central Venous Pressure (CVP) (mmHg)	<sub>1</sub> Not done::::

Other MODS Measurements	continued:				
C10. Glasgow Coma Score		Not done			
a1. Eye opening result	4 = Spontaneous eye opening	☐ 3 = Eye oper	ning to verbal stimuli	2 = Eye opening to pa	in
a2. Best verbal response	☐ 5 = Subject is oriented and conve ☐ 3 = Subject uses inappropriate w		= Subject is disoriente 2 = Subject makes incor		☐ 1 = No response
a3. Best motor response	☐ 6 = Subject obeys command ☐ 3 = Subject has abnormal flexion (decorticate rigidity)		= Subject localizes pair = Subject has extensio		☐ 4 = Subject has flexion withdrawal ☐ 1 = No Response
a4. Total Glasgow Coma S	core:		b. Time Obtained	:	
Additional Measurements:			a. Result	b. Time	Obtained
C11. Whole Blood Lactic Acid	l (mmol/L)	Not done			:
c. Source of Blood		☐ <sub>1</sub> Arterial	☐ <sub>2</sub> Peripheral	☐ <sub>3</sub> Free Flo	wing Venous Catheter or PICC line
C12. Arterial Oxygen Saturation	on (SaO <sub>2</sub> ) (%)	Not done			· 
C13. Systemic Oxygen Satura	tion (Pulse Oximeter Result, SpO <sub>2</sub> ) (%)	Not done			·
C14. Venous Oxygen Saturation	on (PO <sub>2</sub> venous, SvO <sub>2</sub> ) (%)	Not done			_:
C15. Systemic Vascular Resis	tance (SVR) (dynes)	Not done			_:
C16. Pulmonary Capillary Wed	dge Pressure (PCWP) (mmHg)	Not done			_ <b>:</b>
C17. Cardiac Output (L/min)		Not done			_ <b>:</b>
C18. Cardiac Index (L/min/m²)		Not done			·
C19. Oxygen Consumption as	reported on machine/readout (L/min)	Not done			_ <b>:</b>
Components of oxygen con-	sumption calculation (Report if no rea	adout available (	C19) and done within	30 minutes of each other.	.)
C20. Does subject have the 3	components of the oxygen consumption	n calculation obta	ined within 30 minutes	of each other on the day of	assessment? $\square_1$ Yes $\square_2$ No <b>(D1)</b>
Parameter			a. Result	b. Time	Obtained
C21. Arterial Oxygen Saturation	on (SaO2) (%)	Not done			_:
C22. Venous oxygen saturatio	n (SvO <sub>2</sub> ) (%)	Not done			<u>:</u>
C23. Cardiac Output (L/min)		Not done			_:

_	_	_

Section	Section D: MEDICATION CHECKLIST						
D1. Did	the subject receive any of the following medicate	tions on the da	te of assessme	ent?	□₁ Yes	$\square_2$ No <b>(END)</b>	
a.	Abiciximab (ReoPro)	□₁ Yes	$\square_2$ No	p. Therapeutic Heparin (low molecular)	□₁ Yes	□ <sub>2</sub> No	
b.	Aprotinin (Trasylol)	□₁ Yes	$\square_2$ No	q. Hirudin	□₁ Yes	□ <sub>2</sub> No	
c.	Argatroban	□₁ Yes	$\square_2$ No	r. Lepirudin	□₁ Yes	$\square_2$ No	
d.	Aspirin	□₁ Yes	$\square_2$ No	s. Melagatran	□₁ Yes	$\square_2$ No	
e.	Bivalirudin (Angiomax)	□₁ Yes	$\square_2$ No	t. Nitric Oxide Gas	□₁ Yes	$\square_2$ No	
f.	Cilostazol (Pletal)	□₁ Yes	$\square_2$ No	u. Prasugrel (Effient)	□₁ Yes	□ <sub>2</sub> No	
g.	Clopidogrel (Plavix)	□₁ Yes	$\square_2$ No	v. Prothrombin Complex Concentrates	□₁ Yes	□ <sub>2</sub> No	
h.	Dabigatran	□₁ Yes	$\square_2$ No	w. Sildenafil (Viagra)	□₁ Yes	□ <sub>2</sub> No	
i.	Desirudin	□₁ Yes	$\square_2$ No	x. Steroids	□₁ Yes	□ <sub>2</sub> No	
j.	Desmopressin (DDAVP, Stimate, Minirin)	□₁ Yes	$\square_2$ No	y. Ticlopidine (Ticlid)	□₁ Yes	□ <sub>2</sub> No	
k.	Direct Thrombin Inhibitors	□₁ Yes	$\square_2$ No	z. Tirofiban (Aggrestat)	□₁ Yes	□ <sub>2</sub> No	
I.	Epsilon Aminocaproic Acid (Amicar)	□₁ Yes	$\square_2$ No	aa. Tranexamic Acid (Cyklokapron)	□₁ Yes	□ <sub>2</sub> No	
m.	Eptifibatide (Integrilin)	□₁ Yes	$\square_2$ No	bb. Warfarin (Coumadin)	□₁ Yes	□₂ No	
n.	Factor VIIa (NovoSeven)	□₁ Yes	$\square_2$ No	zz. Other anticoagulant or antiplatelet	□₁ Yes	□₂ No	
0.	Therapeutic Heparin (unfractionated)	□₁ Yes	$\square_2$ No	Specify other:		_	

#### Transfusion Medicine/Hemostasis Clinical Trials Network RE09: Post-Op/Daily Measurement Form SECTION A: GENERAL INFORMATION A1. Subject ID A2. Assessment Date SECTION B: LABORATORY RESULTS Record the measurement closest to 7:00 AM. Note: If the Assessment Date is Day 0, record the measurement closest to 7:00 AM but AFTER the end time of surgery. Time Drawn Creatinine (mg/dL) B2. Bilirubin (mg/dL) B3 Platelet Count (x 10^9 L) B4. Hemoglobin (g/L) B5. Fibrinogen (mg/dL) B6. BUN (mg/dL) B7. ALT (SGPT) (U/L) SECTION C: MEASUREMENTS AND INFORMATION Record the measurement closest to 7:00 AM. Note: If the Assessment Date is Day 0, record the measurement closest to 7:00 AM but AFTER the end time of surgery. **General Information:** Did the subject have any of the following lines C1. O Yes O No (C2) in place or an arterial puncture on the assessment date? Pulmonary Artery line/Swan-Ganz catheter C Yes C No b. Arterial line O Yes O No Central venous catheter C. PICC line d. Arterial Puncture C Yes C No C2. Did the subject receive supplemental oxygen at 7:00am? O Yes O No (C3) Oxygen device O Nasal cannula Mask Intubated b. Liters of oxygen received С3. Was the subject on an intra-aortic balloon C Yes C No pump on this day? <u>Other MODS Measurements:</u> C4. Heart Rate Result (beats per minute) a. b. Time Obtained C5. Blood Pressure Systolic Blood Pressure (mmHg) Diastolic Blood Pressure (mmHg) b. Time Obtained **Temporary Save** C6. PO<sub>2</sub> Arterial (PaO<sub>2</sub>, Oxygen level) Save Reload Result (mmHg) Time Obtained b. C7. FiO<sub>2</sub> Result (%) Time Obtained C8. Mean Arterial Pressure

a.	Result (mmHg)			
b.	Time Obtained	ĺ		
C9. Cei	ntral Venous Pressure (CVP)			
a.	Result (mmHg)	J		
b.	Time Obtained			
C10. G	lasgow Coma Score	,		
a1.	Eye Opening Result		C Spor	ontaneous eye opening
				e opening to verbal stimuli
				e opening to pain Response
a2.	Best Verbal Response			oject is oriented and converses
			C Subj	oject is disoriented and converses
				oject uses inappropriate words oject makes incomprehensible sounds
				response
а3.	Best Motor Response		O Subj	oject obeys command
				oject localizes pain
				oject has flexion withdrawal oject has abnormal flexion (decorticate rigidity)
			O Subj	oject has extension (decerebrate rigidity)
			O No r	response
a4.	Total Score	ļ	*	* See note below
b.	Time Obtained			
the ob	ubjects that are sedated during the performing of the GCS r served scores reported for the <u>individual components</u> of the ment of the subject, but the <u>overall score</u> must be given or rather than the sum of the individual component scores.	e GCS	based	on the actual
	Code 88 = <u>Sedated, Expected to Be Normal</u> : had normal n	eurol	ogic fun	inction for age
	by history before surgery and no catastrophic events to cha but currently unable to assess because of sedation.	inge t	hat stat	atus are clinically evident,
•	Code 99 = <u>Sedated, Not Normal</u> : neurologic function not n (prior stroke, tumor or trauma sequelae, cognitively challen			
	intra-operative history, but currently unable to assess beca			
C11. W	<u>onal Measurements:</u> /hole Blood Lactic Acid			
a.	Result (mmol/L)			
b.	Time Drawn			
C.	Source of blood		Arter	erial
			O Perip	
C12 A	rtorial Overgon Saturation (SaO.)		○ Free	e Flowing Venous Catheter or PICC line
	rterial Oxygen Saturation (SaO <sub>2</sub> )  Result (%)			
a.				
	Time Obtained			
	ystemic Oxygen Saturation (Pulse Oximeter Result, SpO	2)		
a.	Result (%)			
b.	Time Obtained			
CECTI	ON D. MEDICATION CHECKLICT			
	ON D: MEDICATION CHECKLIST  ease indicate if the subject received any of Ores Ores	- (ENI	2)	
the	e following medications on the date of sessment.	ואום) כ	))	
		Yes	No	
а.	Abiciximab (ReoPro)	0	0	
b.	Aprotinin (Trasylol)	0	0	
C.	Argatroban	0	0	
d.	Aspirin	0	0	
e.	Bivalirudin (Angiomax)	0	0	
f.	Cilostazol(Pletal)	0	0	
g.	Clopidogrel (Plavix)	0	0	
h.	Dabigatran	0	0	
i.	Desirudin			
j.	Desmopressin (DDAVP, Stimate, Minirin)	0	0	
		0	0	
k.	Direct Thrombin Inhibitors	0	0	

I.	Factor VIIa (NovoSeven)	0	0	
m.	Epsilon Aminocaproic Acid (Amicar)	0	0	
n.	Eptifibatide (Integrilin)	0	0	
Ο.	Therapeutic heparin (unfractionated)	0	0	
p.	Therapuetic heparin (low molecular)	0	0	
q.	Hirudin	0	0	
r.	Lepirudin	0	0	
s.	Melagatran	0	0	
t.	Nitric Oxide Gas	0	0	
u.	Prasugrel (Effient)	0	0	
V.	Prothrombin Complex Concentrates	0	0	
w.	Sildenafil (Viagra)	0	0	
х.	Steroids	0	0	
у.	Ticlopidine (Ticlid)	0	0	
Z.	Tirofiban (Aggrestat)	0	0	
aa.	Tranexamic Acid (Cyklokapron)	0	0	
bb.	Warfarin (Coumadin)	0	0	
ZZ.	Other anticoagulant or antiplatelet	0	0	
	Specify other			
			_	
			∞[	
	<u>'</u>		_	

DONE

RE10: RBC Product Form Version: A

SECTION A: GENERAL INFORMATION	
A1. Subject ID	
A2. Date RBC unit issued	
A3. Time RBC unit issued	
SECTION B: RBC PRODUCT INFORMATION	
B1. Unit ID Number	
B2. Source of unit	C Apheresis C Whole blood collection
B3. ABO group of unit	C A
	O B
	O AB
B4. Rh type	C Positive C Negative
B5. Collection Date	
B6. Storage medium	C AS1
	C AS3
	<ul><li>AS5</li><li>CPDA1 (Protocol Deviation)</li></ul>
	Other (Protocol Deviation)
a. Specify other	
	<u>^</u>
B7. Was the unit irradiated?	C Yes C No (B8)
a. Date of irradiation	
b. Time of irradiation	
B8. Was the unit leukoreduced?	○ Yes ○ No (Protocol Deviation)
B9. Was the unit washed?	C Yes (Protocol Deviation) C No (B10)
a. Date unit washed	
b. Time unit washed	
B10. Was this a non-study unit for one of the reasons listed below?	C Yes (Protocol Deviation) C No (END)
Check all that apply:	
a. Autologous	
b. Directed donation	

c. Deglycerolized	П	
d. Frozen	П	
DONE		

RE10: RBC Product Form Version: B

SEC	TION A: GENERAL INFORMATION			
A1. 9	A1. Subject ID			
A2. Date RBC unit issued				
A3. 7	Fime RBC unit issued			
SEC	TION B: RBC PRODUCT INFORMATION			
B1.	Unit ID Number			
B2	Source of unit	C. Anhaussia. C. Whala bland cellection		
	ABO group of unit	<ul><li>Apheresis</li><li>Whole blood collection</li></ul>		
55.	The group of anic	O B		
		O AB		
		0 0		
B4.	Rh type	O Positive O Negative		
B5.	Collection Date			
В6.	Storage medium	O AS1		
	_	O AS3		
		O AS5		
		CPDA1 (Protocol Deviation)		
		Other (Protocol Deviation)		
	a. Specify other			
		<u> </u>		
		_		
B7.	Was the unit irradiated?	○ Yes ○ No (B8)		
a.	Date of irradiation			
b.	Time of irradiation			
B8.	Was the unit leukoreduced?	C Yes C No (Protocol Deviation)		
В9.	Was the unit washed?	C Yes (Protocol Deviation) C No (B10)		
a.	Date unit washed			
b.	Time unit washed			
B10.	Was the unit volume reduced?	C Yes (Protocol Deviation) C No		
B11.	Was this a non-study unit for one of the reasons listed below?	C Yes (Protocol Deviation) C No (END)		
	Check all that apply:			
	a. Autologous			

b. Directed donation		
c. Deglycerolized		
d. Frozen		
DONE		



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#### Form RE11 - RBC Transfusion Administration Data Worksheet

Section A: GENERAL INFORMATION		
A1. Subject ID:		
Section B: RBC PRODUCT ADMINISTRATION		
B1. Unit ID Number		
B2. Was the unit given intraoperatively? $\square_1$ Yes $\square_2$ No		
B3. Transfusion start date/ / (mm/dd/yyyy)		
B3a. Transfusion start time (24 hour clock)		
B4. Was the entire unit transfused? $\square_1$ Yes <b>(B5)</b> $\square_2$ No		
B4a. Estimated volume transfused (mL)		
B5. Was the unit washed after it was released from the Blood Bank?		
$\square_1$ Yes (Protocol Deviation) $\square_2$ No <b>(END)</b> $\square_3$ Unknown <b>(END)</b>		
B5a. Date unit washed//(mm/dd/yyyy)		
B5b. Time unit washed : (24 hour clock)		

RE12: Transfusion	n of Other Blood Products Form Version: A
SECTION A: GENERAL INFORMATION	
A1. Subject ID	
SECTION B: BLOOD PRODUCT ADMINISTRATION	
B1. Type of product transfused	<ul><li>Apheresis Platelets(B4a)</li><li>Whole Blood Derived Platelets(B4b)</li><li>Plasma(B4c)</li><li>Cryoprecipitate(B4b)</li></ul>
a. Was the unit(s) leukoreduced?	C Yes C No
B2. Was the unit(s) given intraoperatively?	○ Yes ○ No
B3. Transfusion Start Date	
a. Transfusion Start Time	
B4. a. Number of whole blood unit equivalents	
b. Number of units pooled	
c. Number of units	
B5. Was the entire unit transfused?	O Yes (END) O No
a. Estimated percent of unit volume transfused (m	nL)
DONE	

Transfusion Medicine	e/Hemostasis Clinical Trials Network		
	RE13: EKG Form Version: A		
SECTION A: GENERAL INFORMATION			
A1. Subject ID			
A2. Time point	© Pre-Op © Post-Op © Intra-Op		
SECTION B: 12-LEAD ELECTROCARDIOGRAM DATA			
B1. Date of EKG			
B2. Time of EKG			
B3. Identifier			
DONE			

Transfusion Medicine/Hemostasis Clinical Trials Network  RE15: Laboratory Measurement Form-Day 7  Version: A
SECTION A: GENERAL INFORMATION
SECTION A. GENERAL INFORMATION
A1. Subject ID
A2. Date of Blood Draw
A3. Time of Blood Draw
SECTION B: LABORATORY DATA
B1. Platelet Count (x 10^9 L)
B2. Hemoglobin (g/L)
B3. Creatinine (mg/dL)
B4. Bilirubin (mg/dL)
B5. ALT (SGPT) (U/L)
B6. Fibrinogen (mg/dL)
DONE
DORE

Transfusion Medicine/Hemostasis Clinical Trials Network			
RE18: Contact Form (Telephone Follow-up)  Version: A			
SECTION A: GENERAL INFORMATION			
A1. Subject ID			
SECTION B: TELEPHONE CONTACT INFO	DRMATION		
B1. Interview disposition code	v v		
B2. Mode of contact	<ul><li>Telephone</li><li>Face-to-face</li></ul>		
B3. Number of calls			
B4. Date of contact			
B5. Interviewer initials			
B6. Comment			
DONE			

RE24: Troponin-I Results Form

Version: A		
SECTION A: GENERAL INFORMATION		
A1. Subject ID		
A2. a. Local Troponin I upper limit of normal for this subject Less than (<)  Equal •(o (=)		
b. Troponin I value (ng/mL)		
SECTION B: TROPONIN RESULTS		
Record the following Troponin-I results on this form:		
Required Results (must be ordered per study requirements):		
<ul> <li>Daily Troponin-I result obtained closest to 7:00 am on Day 0 through Day 7, hospital discharge or death, whichever comes first.</li> <li>If hospitalized after day 7, Troponin-I result obtained closest to 7:00 am on Day 28 or discharge, whichever comes first.</li> </ul>		
Additional Results (may be ordered, if any were done):		
<ul> <li>Additional Troponin-I results obtained Day 0 – Day 7 that are 5 times the upper limit of normal or higher.</li> <li>Daily Troponin-I results obtained closest to 7:00 am on Days 8-27 done as part of standard of care.</li> </ul>		
B1. a. Troponin I result (ng/mL)		
B1. b. Date Drawn		
B1. c. Time Drawn		
DONE		

RE24: Troponin-I Results Form Version: B

SECTION A: GENERAL INFORMATION			
A1. Subject ID			
A2. a. Local Troponin I upper limit of normal for this subject	Loss than (>)		
	Equal to (=)		
b. Troponin I value (ng/mL)			
SECTION B: TROPONIN RESULTS			
Record the following Troponin-I results on this form:			
Required Results (must be ordered per study requirements	<u>s)</u> :		
Pre-op Troponin-I result obtained closest to the start	time of surgery and within 30 days prior to		
<ul> <li>surgery.</li> <li>Daily Troponin-I result obtained closest to 7:00 am or</li> </ul>	n Day 0 through Day 7, hospital discharge or death,		
<ul> <li>whichever comes first.</li> <li>If hospitalized after day 7, Troponin-I result obtained closest to 7:00 am on Day 28 or discharge, whichever comes first.</li> </ul>			
Additional Results (may be ordered, if any were done):			
<ul> <li>Additional Troponin-I results obtained Day 0 – Day 7 that are 5 times the upper limit of normal or higher.</li> <li>Daily Troponin-I results obtained closest to 7:00 am on Days 8-27 done as part of standard of care.</li> </ul>			
B1. a. Troponin I result (ng/mL)	Less than (<)		
	Equal to (=)		
	Greater than (>)		
B1. b. Date Drawn			
B1. c. Time Drawn			
DONE			

RE25: Hospital Discharge Form Version: A

SECTION A: GENERAL INFORMATION	
A1. Subject ID	
SECTION B: POST-OPERATIVE PROCEDURES	
B1. Was a balloon pump inserted post-operatively	? C Yes C No
B2. Days to first BM	
B3. Days to first solid food	
B4. Date of ICU discharge	
a. Time of ICU discharge	
B5. Was the subject readmitted to the ICU?	O Yes O No
a. Date readmitted to ICU	
b. Time readmitted to ICU	
B6. Initial date extubated	
a. Initial time extubated	
B7. Was the subject reintubated?	C Yes C No
a. Date intubated	
b. Time intubated	
c. Date extubated	
d. Time extubated	
B8. Discharge date	
SECTION C: MEDICATIONS	
C1. Did the subject receive any of the following agents 48 hours post surgery or later?	○ Yes ○ No (END)
C2. Epinephrine	○ Yes ○ No
C3. Norepinephrine	○ Yes ○ No
C4. Vasopressin	○ Yes ○ No
C5. Dopamine > 3 mcg/kg/min	○ Yes ○ No
C6. Dobutamine	○ Yes ○ No
C7. Milrinone	○ Yes ○ No

C8. Amrinone	C Yes C No	
C9. Phenylephrine	O Yes O No	
DONE		

Transfusion Me	dicine/Hemostasis Clinical Trials Network	
	RE26: End of Study Form	
	Version: A	
SECTION A: GENERAL INFORMATION		
A1. Subject ID		
CECTION D. FND OF CTUDY INFORMATI	ON	
SECTION B: END OF STUDY INFORMATI B1. What was the primary reason for the e		
<ul><li>Completion of 28 day follow-up (Su</li><li>Subject (or guardian) decision to w</li></ul>		
© Death		
Physician decision to withdraw sub	ject	
C Study terminated at site		
<ul><li>Entire study terminated</li><li>Subject did not receive a RBC transfusion intra-operatively or within the first 96 hours after surgery</li></ul>		
C Lost to follow-up		
No surgery for 30 days		
Other		
a. Specify other		
	A	
B2. End of Study/Date of Death		
B3. Comments		
	<u>A</u>	
DONE		



TMH - 08: RECESS

### Form RE26 – End of Study Worksheet

Section A: GENERAL INFORMATION					
A1. Subject ID:					
O a Care D. END OF OTHER INFORMATION					
Section B: END OF STUDY INFORMATION					
B1. What was the primary reason for the end of study?					
☐₁ Completion of 28 day follow-up (subject alive at Day 28)					
$\square_2$ Subject (or guardian) decision to withdraw					
☐₃ Death					
☐ <sub>4</sub> Physician decision to withdraw subject					
☐₅ Study terminated at site					
☐ <sub>6</sub> Entire study terminated					
$\square_{7}$ Subject did not receive an RBC transfusion between randomization and 96 hours after the end of surgery					
☐ <sub>8</sub> Lost to follow-up					
☐ <sub>9</sub> No surgery for 30 days					
□ <sub>10</sub> Other					
B1a. Specify other reason:					
B1b. What was the primary cause of death:					
B2. End of Study Date/Date of Death: / / (mm/dd/yyyy)					
B3. Comments:					

RE80: Myocardial Infarction Event Form Version: A

SECTION A: GENERAL INFORMATION				
A1. Subject ID				
SECTION B: ADVERSE EVENT INFORMATION				
B1. Adverse Event (record diagnosis)				
a Adverse Event (MedDDA setegory)	▼			
a. Adverse Event (MedDRA category)				
	₩			
B2. a. Date of Onset				
b. Time of Onset				
B3. Assessment Date				
B4. Intensity	C Mild			
	© Moderate © Severe			
B5. Relationship to RBC transfusion	© Not related			
	C Possibly related			
	© Probably related © Related			
Clinical Evidence:				
B6. a. Troponin I level (ng/mL)				
b. Date of Troponin I level				
c. Upper limit of normal for institution (ng/mL)				
B7. Was a 12 lead EKG performed?	C Yes C No (B8a)			
a. Date 12 lead EKG performed				
b. Time 12 lead EKG performed				
B8. What was the treatment for this event? Answer all questions.				
a. None (Observation)	Yes No			
c (0230. validity				
b. Procedure (If yes, discuss procedure in narrative)	0 0			
c. Medication (If yes, discuss medication in narrative)	0 0			

d. Other (If yes, discuss other in narrative)	O O			
d1. Specify other				
B9. Outcome	<ul> <li>Resolved without sequelae</li> <li>Resolved with sequelae</li> <li>Not resolved (B10)</li> <li>Not resolved at death (B10)</li> </ul>			
a. Date of resolution				
B10. What, if any, of the following serious criteria were met with this event? Answer all questions.				
	Yes No			
a. Life-threatening	0 0			
<ul> <li>Requires hospitalization or prolongation of existing hospitalization</li> </ul>	0 0			
<ul> <li>c. Results in a persistent or significant disability/incapacitation</li> </ul>	O O			
d. Medically important event	O O			
e. Results in a congenital anomaly/birth defect	0 0			
f. Results in death	0 0			
f1. Date of death				
B11. Was the subject withdrawn from the study due to Yes No this event?				
B12. Brief description of clinical presentation, treatment and evolution of event, and any other assessments (e.g. laboratory data) which help explain the event and have not been recorded elsewhere on this form. If the outcome of the SAE was death, write cause of death.				
	<u> </u>			
	▼			
DONE				

RE80: Myocardial Infarction/Cardiac Ischemia/Elevated Cardiac Marker Event Form Version: B

SECTION A: GENERAL INFORMATION		
SECTION A: GENERAL INFORMATION		
A1. Subject ID		
SECTION B: EVENT INFORMATION		
B1. Adverse Event (record diagnosis)		
		▲
a. Adverse Event (MedDRA category)		
		(If not found enter -6)
B2. a. Date of Onset		
b. Time of Onset		
B3. Assessment Date		
B4. Intensity/Grade of this event:		C Mild/Grade 1
B5. Relationship to RBC transfusion		<ul> <li>Moderate/Grade 2</li> <li>Severe/Grade 3</li> <li>Life threatening/Grade 4</li> <li>Death/Grade 5</li> <li>Not related</li> </ul>
		C Possibly related C Probably related C Related
Clinical Evidence:		
B6. a. Troponin I level (ng/mL)		
b. Date of Troponin I level		
c. Time Troponin I level obtained		
d. Upper limit of normal for institution (ng/mL)		
B7. Was a 12 lead EKG performed?		C Yes C No (B8a)
a. Date 12 lead EKG performed		
b. Time 12 lead EKG performed		
B8. What was the treatment for this event? Answer all questions.		
a. None (Observation)	Yes	No ©
b. Procedure (If yes, discuss procedure in narrative)	0	©

c. Medication (If yes, discuss medication in narrative)	o o	
d. Other (If yes, discuss other in narrative)	0 0	
d1. Specify other		
	<u></u>	
B9. Outcome	Resolved without sequelae	
	Resolved with sequelae	
	<ul><li>Not resolved (B10)</li></ul>	
	<ul><li>Not resolved at death (B10)</li></ul>	
a. Date of resolution		
B10. What, if any, of the following serious criteria we	ere met with this event? Answer all questions.	
	Yes No	
a. Life-threatening	0 0	
<ul> <li>Requires hospitalization or prolongation of existing hospitalization</li> </ul>	0 0	
<ul> <li>c. Results in a persistent or significant disability/incapacitation</li> </ul>	o o	
d. Medically important event	0 0	
e. Results in a congenital anomaly/birth defect	0 0	
f. Results in death	o o	
f1. Date of death		
B11. Was the subject withdrawn from the study due to this event?	○ Yes ○ No	
B12. Brief description of clinical presentation, treatment and evolution of event, and any other assessments (e.g. laboratory data) which help explain the event and have not been recorded elsewhere on this form. If the outcome of the SAE was death, write cause of death.		
	A	
	▼	
DONE		

RE80: Myocardial Infarction/Cardiac Ischemia/Elevated Cardiac Marker Event Form Version: C

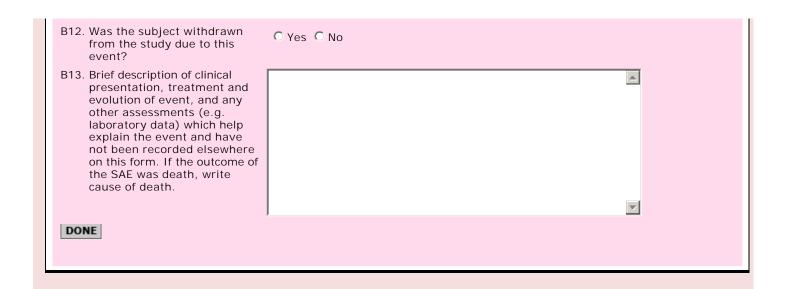
SECTION A: GENERAL INFORMATION					
A1.	Subject ID				
SEC	CTION B: EVENT INFORMATION				
B1.	Adverse Event (record diagnosis)				
		_			
	a. Adverse Event (MedDRA category)	<u> </u>			
	(If not found enter -6)	<u>×</u>			
B2.	a. Date of Onset				
	b. Time of Onset				
В3.	Assessment/Report Date				
B4.	Intensity/Grade of this event:	© Mild/Grade 1			
		<ul> <li>Mind/Grade 1</li> <li>Moderate/Grade 2</li> <li>Severe/Grade 3</li> <li>Life threatening/Grade 4</li> <li>Death/Grade 5</li> </ul>			
B5.	Relationship to RBC transfusion	C Not related C Possibly related C Probably related C Related			
Clin	ical Evidence:				
B6.	a. Troponin I level (ng/mL)				
	b. Date of Troponin I level				
	c. Time Troponin I level obtained				
	d. Upper limit of normal for institution (ng/mL)				
B7.	Was a 12 lead EKG performed?	○ Yes ○ No (B8a)			
	a. Date 12 lead EKG performed				
	b. Time 12 lead EKG performed				
B8.	What was the treatment for this event? Answer all quantum and the second of the second				
		Yes No			

	a. None (Observation)	0	
	b. Procedure (If yes, discuss procedure in narrative)	0	ullet
	c. Medication (If yes, discuss medication in narrative)	0	•
	d. Other (If yes, discuss other in narrative)	0	0
	d1. Specify other		
			_
B9.	Outcome	0	Resolved without sequelae Resolved with sequelae Not resolved (B10)
			Not resolved at death (B10)
	a. Date of resolution		
B10	D. What, if any, of the following serious criteria were		·
	a. Life-threatening		No O
	b. Requires hospitalization or prolongation of existing hospitalization		•
	c. Results in a persistent or significant disability/incapacitation	0	О
	d. Important Medical Event Any adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other serious adverse event criteria (10a-c, e-f).	0	•
	e. Results in a congenital anomaly/birth defect	0	•
	f. Results in death	0	0
	f1. Date of death		
	What, if any, of the following unexpected and unanger    wer all questions.	ticipa	ted event criteria were met with this event?
		Yes	No
а	Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol, consent form, and other study documents, and (b) the characteristics of the subject population being studied and the expected natural progression of any underlying disease, disorder, or condition.	0	C
b	Related or possibly related to a subject's participation in the research	0	0
C.	Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.	0	•

B12.	Was the subject withdrawn from the study due to this $_{\!$
	Brief description of clinical presentation, treatment and evolution of event, and any other assessments (e.g. laboratory data) which help explain the event and have not been recorded elsewhere on this form.  If the outcome of the SAE was death, write cause of death.
DON	E

	RE81: Infection/Sepsis Event Form Version: A
SECTION A: GENERAL INFORMATI	ION
A1. Subject ID	
SECTION B: ADVERSE EVENT INFO	ORMATION
B1. Adverse Event (record diagnosis)	
a. Adverse Event (MedDRA category)	
B2a. Date of Onset	
B2b. Time of Onset	
B3. Assessment Date	
B4. Intensity	C Mild Moderate Severe
B5. Relationship to RBC transfusion	C Not related C Possibly related C Probably related C Related
B6. Did the subject have a localized infection?	C Yes C No (B7)
a. Infection Category	C Abdominal/Pelvic C Gastrointestinal C IV Catheter C Mediastinum C Pneumonia C Urinary Tract C Other localized infection
a1. Specify other	
B7. Did the subject have sepsis (i.e., a blood or systemic infection)?	C Yes C No (B8a)
<ul><li>a. Was a positive culture from blood and/or CSF obtained?</li></ul>	C Yes C No (B8a)
b. Date of culture	
c. Site(s) of culture	© Blood © Cerebrospinal fluid

		© Blo	ood and Cerebrospinal fluid
d. Oı	rganism(s)		
			w
			_
B8.			Did the subject have any of the following +/- 24 hours of the
diagno	sis of sepsis?		
		Yes	No
Ce	emperature < 36 degrees elsius or > 38 degrees elsius?	0	•
b. He	eart rate > 90 bpm?	0	•
br	espiration rate > 20 eaths/min or PaCO2 < 2mmHg?	0	•
12	hite blood cell count > 2,000 or < 4000 cell/mm3 or 10% bands?	0	C
RO W	hat was the treatment for thi	s aver	nt2 Answer all guestions
D9. VV	nat was the treatment for the	Yes	No
a Ne	one (observation)		
a. IN	one (observation)	0	C
pr	ocedure (If yes, discuss ocedure in narrative)	•	C
	edication (If yes, discuss edication in narrative)	0	O
d. O	ther (If yes, discuss other in arrative)	0	0
d1	I. Specify other		
			V
B10. O	utcome	© Res	solved without sequelae
			solved with sequelae
			t resolved (B11a)
		O Not	t resolved at death (B11a)
a. Da	ate event resolved		
B11. W	/hat, if any, of the following	seriou	us criteria were met with this event? Answer all questions.
		Yes	No
a. Li	fe-threatening	0	O
pr	equires hospitalization or olongation of existing ospitalization	0	O
c. Pe	ermanent sability/incapacitation	0	<b>O</b>
	edically important event	0	•
e. Re ar	esults in a congenital nomaly/birth defect	0	С
f. Re	esults in death	0	•
f1	. Date of death		



	RE81: Infection/Sepsis Event Form Version: B
	Version. D
SECTION A: GENERAL INFORMAT	ION
A1. Subject ID	
SECTION B: ADVERSE EVENT INFO	ORMATION
B1. Adverse Event (record diagnosis)	
diagnosis)	
a. Adverse Event (MedDRA	
category)	
	(If not found enter -6)
B2a. Date of Onset	(If not round enter -0)
B2b. Time of Onset	
B3. Assessment Date	
B4. Intensity/Grade of this event:	
54. Intensity/Grade of this event.	○ Mild/Grade 1
	<ul><li>Moderate/Grade 2</li><li>Severe/Grade 3</li></ul>
	C Life Threatening/Grade 4
	O Death/Grade 5
B5. Relationship to RBC	○ Not related
transfusion	© Possibly related
	© Probably related
	○ Related
B6. Did the subject have a localized infection?	○ Yes ○ No (B7)
a. Infection Category	C Abdominal/Pelvic
	© Gastrointestinal
	C IV Catheter
	○ Mediastinum
	<ul><li>Pneumonia</li><li>Urinary Tract</li></ul>
	Other localized infection
a1. Specify other	
, , , , , ,	
	▼
B7. Did the subject have sepsis (i.e., a blood or systemic infection)?	○ Yes ○ No (B8a)
<ul><li>a. Was a positive culture from blood and/or CSF obtained?</li></ul>	○ Yes ○ No (B8a)

b. Date of culture		
c. Site(s) of culture	© Blood © Cerebrospinal fluid	
	© Blood and Cerebrospinal fluid	
d. Organism(s)	_	
B8. diagnosis of sepsis?	Did the subject have any of the following $+/-24$ hours or	f the
	Yes No	
<ul><li>a. Temperature &lt; 36 degrees</li><li>Celsius or &gt; 38 degrees</li><li>Celsius?</li></ul>	<b>o</b> o	
b. Heart rate > 90 bpm?	o o	
<ul><li>c. Respiration rate &gt; 20 breaths/min or PaCO2 &lt; 32mmHg?</li></ul>	• •	
d. White blood cell count > 12,000 or < 4000 cell/mm3 or > 10% bands?	<b>O</b> O	
B9. What was the treatment for th	this event? Answer all questions	
by. What was the treatment for the	Yes No	
a. None (observation)	• •	
<ul><li>b. Procedure (If yes, discuss procedure in narrative)</li></ul>	0 0	
<ul> <li>Medication (If yes, discuss medication in narrative)</li> </ul>	0 0	
<ul> <li>d. Other (If yes, discuss other in narrative)</li> </ul>	o o	
d1. Specify other		
B10. Outcome		
B10. Outcome	<ul><li>Resolved without sequelae</li><li>Resolved with sequelae</li></ul>	
	© Not resolved (B11a)	
	O Not resolved at death (B11a)	
a. Date event resolved		
P11 What if any of the faller-in-	g serious criteria were met with this event? Answer all questions.	
BII. What, if any, of the following	Yes No	
a. Life-threatening	0 0	
b. Requires hospitalization or		
prolongation of existing hospitalization	O O	
<ul><li>c. Permanent disability/incapacitation</li></ul>	0 0	
d. Medically important event	o o	

e. Results in a congenital anomaly/birth defect	©
f. Results in death	0 0
f1. Date of death	
B12. Was the subject withdrawn from the study due to this event?	○ Yes ○ No
B13. Brief description of clinical presentation, treatment and evolution of event, and any other assessments (e.g. laboratory data) which help explain the event and have not been recorded elsewhere on this form. If the outcome of the SAE was death, write cause of death.	
DONE	

RE81: Infection/Sepsis Event Form
Version: C

	Version: C	
SECTION A: GENERAL INFORMA	ATION	
A1. Subject ID		
SECTION B: ADVERSE EVENT IN	NFORMATION	
B1. Adverse Event (record diagnosis)		
		<b>▽</b>
<ul> <li>a. Adverse Event (MedDRA category)</li> </ul>		_
		$\overline{\mathbf{v}}$
B2a. Date of Onset	(If not found enter -6)	
B2b. Time of Onset		
B3. Assessment/Report Date		
B4. Intensity/Grade of this		
event:	<ul><li>Mild/Grade 1</li><li>Moderate/Grade 2</li></ul>	
	C Severe/Grade 3	
	C Life Threatening/Grade 4 C Death/Grade 5	
B5. Relationship to RBC	C Not related	
transfusion	C Possibly related	
	<ul><li>Probably related</li><li>Related</li></ul>	
B6. Did the subject have a localized infection?	C Yes C No (B7)	
a. Infection Category	C Abdominal/Pelvic	
	C Gastrointestinal C IV Catheter	
	© Mediastinum	
	C Pneumonia	
	<ul><li>Urinary Tract</li><li>Other localized infection</li></ul>	
a1. Specify other		
		V
B7. Did the subject have sepsis	C Yes C No (B8a)	
(i.e., a blood or systemic infection)?		
<ul> <li>a. Was a positive culture from blood</li> </ul>	C Yes C No (B8a)	

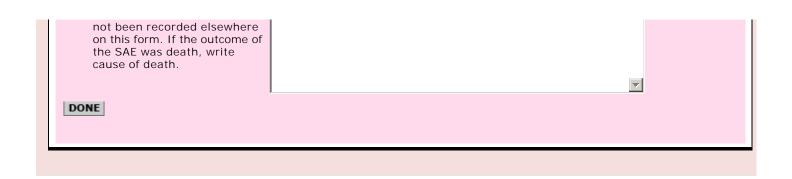
and/or CSF obtained?	
b. Date of culture	
c. Site(s) of culture	<ul><li>Blood</li><li>Cerebrospinal fluid</li><li>Blood and Cerebrospinal fluid</li></ul>
d. Organism(s)	A V
B8. the diagnosis of infection?	Did the subject have any of the following +/- 24 hours of
	Yes No
<ul><li>a. Temperature &lt; 36 degrees</li><li>Celsius or &gt; 38 degrees</li><li>Celsius?</li></ul>	O O
b. Heart rate > 90 bpm?	o o
c. Respiration rate > 20 breaths/min or PaCO2 < 32mmHg?	O O
d. White blood cell count > 12,000 or < 4000 cell/mm3 or > 10% bands?	O O
B9. What was the treatment fo	r this event? Answer all questions.
	Yes No
a. None (observation)	о о
<ul><li>b. Procedure (If yes, discuss procedure in narrative)</li></ul>	O O
c. Medication (If yes, discuss medication in narrative)	O O
d. Other (If yes, discuss other in narrative)	o o
d1. Specify other	
	▼
B10. Outcome	© Resolved without sequelae
	© Resolved with sequelae
	<ul><li>Not resolved (B11a)</li><li>Not resolved at death (B11a)</li></ul>
a. Date event resolved	Not resolved at death (BTTa)
a. Date event resolved	
B11. What, if any, of the follow	ing serious criteria were met with this event? Answer all questions.  Yes No
a. Life-threatening	0 0
b. Requires hospitalization or prolongation of existing	0 0
hospitalization c. Permanent	
disability/incapacitation	0 0

e. Results in a congenital anomaly/forth defect  f. Results in death  f1. Date of death  F1. Date of death  F1. Date of death  F2. What, if any, of the following unexpected and unanticipated event criteria were met with this event? Answer all questions.  Yes No  a. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol, consent form, and other study documents, and (b) the characteristics of the subject population being studied and the expected natural progression of any underlying disease, and the expected natural progression of any underlying disease, and the expected natural progression of any underlying disease, and the expected natural progression of any underlying disease, and the expected natural progression of any underlying disease, and the expected natural progression of any underlying disease, and the expected natural progression of any underlying disease, and the expected to a subject's participation in the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.  B13. Was the subject withdrawn from the study due to this event?  Yes No expected and unanticipated event criteria were met with this event?  Yes No  Yes No  Yes No  Yes No  E4 Brief description of clinical presentation, treatment and evolution of event, and any other assessments (e.g.) laboratory data) which help explain the event and have not been recorded elsewhere on this form. If the outcome of the SAE was death, write cause of death.	u.	Important Medical Event Any adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other serious adverse event criteria (11a-c, e-f).	•	С	
B12. What, if any, of the following unexpected and unanticipated event criteria were met with this event?  Answer all questions.  Yes No  a. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol, consent form, and other study documents, and (b) the characteristics of the subject population being studied and the expected natural progression of any underlying disease, disorder, or condition.  b. Related or possibly related to a subject's participation in the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.  B13. Was the subject withdrawn from the study due to this event?  B14. Brief description of clinical presentation, treatment and evolution of event, and any other assessments (e.g. flaboratory data) which help explain the event and have not been recorded elsewhere on this form. If the outcome of the SAE was death, write cause of death.	e.		0	0	
B12. What, if any, of the following unexpected and unanticipated event criteria were met with this event?  Answer all questions.  Yes No  a. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol, consent form, and other study documents, and (b) the characteristics of the subject population being studied and the expected natural progression of any underlying disease, disorder, or condition.  b. Related or possibly related to a subject's participation in the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.  B13. Was the subject withdrawn from the study due to this event?  B14. Brief description of clinical presentation, treatment and evolution of event, and any other assessments (e.g., laboratory data) which help explain the event and have not been recorded elsewhere on this form. If the outcome of the SAE was death, write cause of death.	f.	Results in death	0	0	
Answer all questions.  Yes No  a. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol, consent form, and other study documents, and (b) the characteristics of the subject population being studied and the expected natural progression of any underlying disease, disorder, or condition.  b. Related or possibly related to a subject's participation in the research  C. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.  B13. Was the subject withdrawn from the study due to this event?  B14. Brief description of clinical presentation, treatment and evolution of event, and any other assessments (e.g., laboratory data) which help explain the event and have not been recorded elsewhere on this form. If the outcome of the SAE was death, write cause of death.		f1. Date of death			
a. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol, consent form, and other study documents, and (b) the characteristics of the subject population being studied and the expected natural progression of any underlying disease, disorder, or condition.  b. Related or possibly related to a subject's participation in the research  c. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.  B13. Was the subject withdrawn from the study due to this event?  B14. Brief description of clinical presentation, treatment and evolution of event, and any other assessments (e.g., laboratory data) which help explain the event and have not been recorded elsewhere on this form. If the outcome of the SAE was death, write cause of death.			ng une	expected	d and unanticipated event criteria were met with this event?
nature, severity, or frequency) given (a) the research procedures that are described in the protocol, consent form, and other study documents, and (b) the characteristics of the subject population being studied and the expected natural progression of any underlying disease, disorder, or condition.  b. Related or possibly related to a subject's participation in the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.  B13. Was the subject withdrawn from the study due to this event?  B14. Brief description of clinical presentation, treatment and evolution of event, and any other assessments (e.g. laboratory data) which help explain the event and have not been recorded elsewhere on this form. If the outcome of the SAE was death, write cause of death.			Yes	No	
to a subject's participation in the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.  B13. Was the subject withdrawn from the study due to this event?  B14. Brief description of clinical presentation, treatment and evolution of event, and any other assessments (e.g. laboratory data) which help explain the event and have not been recorded elsewhere on this form. If the outcome of the SAE was death, write cause of death.	a.	nature, severity, or frequency) given (a) the research procedures that are described in the protocol, consent form, and other study documents, and (b) the characteristics of the subject population being studied and the expected natural progression of any underlying disease,	O	•	
places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.  B13. Was the subject withdrawn from the study due to this event?  B14. Brief description of clinical presentation, treatment and evolution of event, and any other assessments (e.g. laboratory data) which help explain the event and have not been recorded elsewhere on this form. If the outcome of the SAE was death, write cause of death.	b.	to a subject's participation	0	0	
from the study due to this event?  B14. Brief description of clinical presentation, treatment and evolution of event, and any other assessments (e.g. laboratory data) which help explain the event and have not been recorded elsewhere on this form. If the outcome of the SAE was death, write cause of death.	C.	places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or	•	•	
presentation, treatment and evolution of event, and any other assessments (e.g. laboratory data) which help explain the event and have not been recorded elsewhere on this form. If the outcome of the SAE was death, write cause of death.	B13	from the study due to this	O Ye	es C No	0
DONE	B14	presentation, treatment and evolution of event, and any other assessments (e.g. laboratory data) which help explain the event and have not been recorded elsewhere on this form. If the outcome of the SAE was death, write cause of			
	DO	NE			

RE82: Renal Failure Event Form Version: A

Version: A	
SECTION A: GENERAL INFORMATION	
A1. Subject ID	
SECTION B: ADVERSE EVENT INFORMATION	
B1. Adverse Event (record diagnosis)	<u></u>
	V
a. Adverse Event (MedDRA category)	A.
	<b>V</b>
a. Date of Onset	
b. Time of Onset	
B3. Assessment Date	
B4. Intensity C Mild	
○ Moderate ○ Severe	
B5. Relationship to RBC	
transfusion C Possibly related	
© Probably related © Related	
B6. Has the subject experienced any of the following:	
a. Increase in creatinine to 3x baseline?   O Yes O No (B6b)	
Baseline creatinine level (mg/dL)	
2. Date of baseline creatinine level assessment	
3. Time of baseline creatinine level assessment	
4. Peak creatinine level (mg/dL)	
5. Date of peak creatinine level assessment	
6. Time of peak creatinine level assessment	
b. Absolute creatinine greater than or equal to 4.0 mg/dL with acute rise of >0.5 mg/dL?	
1. Creatinine level (mg/dL)	
2. Date of creatinine assessment	
3. Time of creatinine assessment	

	4. Prior creatinine level (mg/dL)		
	5. Date of prior creatinine assessment		
	6. Time of prior creatinine assessment		
C.	Dialysis?	○ Yes ○ No (B6d)	
	1. Date dialysis initiated		
d.	Hemofiltration?	C Yes C No (B7a)	
	1. Date hemofiltration initiated		
B7.	What was the treatment for the	this event? Answer all questions.	
a.	None (Observation)	Yes No	
b.	Procedure (If yes, discuss procedure in narrative)	o o	
C.	Medication (If yes, discuss medication in narrative)	0 0	
d.	Other (If yes, discuss other in narrative)	o o	
	1. Specify other		
B8.	Outcome	© Resolved without sequalea	
		C Resolved with sequelae C Not resolved (B9a)	
	Data avent received	C Not resolved at death (B9a)	
	Date event resolved		
В8.	what, if any, the following ser	erious criteria were met with this event? Answer all questions.	
		Yes No	
a.	Life-threatening	Yes No	
	Life-threatening  Requires hospitalization or prolongation of existing hospitalization		
b.	Requires hospitalization or prolongation of existing hospitalization Results in a persistent or significant	0 0	
b. c.	Requires hospitalization or prolongation of existing hospitalization Results in a persistent or	<ul><li>O</li><li>O</li><li>O</li></ul>	
b. c. d.	Requires hospitalization or prolongation of existing hospitalization  Results in a persistent or significant disability/incapacitation		
b. c. d. e.	Requires hospitalization or prolongation of existing hospitalization  Results in a persistent or significant disability/incapacitation  Medically important event  Results in a congenital		
b. c. d. e.	Requires hospitalization or prolongation of existing hospitalization  Results in a persistent or significant disability/incapacitation  Medically important event  Results in a congenital anomaly/birth defect		
b. c. d. e.	Requires hospitalization or prolongation of existing hospitalization  Results in a persistent or significant disability/incapacitation  Medically important event  Results in a congenital anomaly/birth defect  Results in death		



RE82: Renal Failure Event Form

		Version: B
SEC	TION A: GENERAL INFORMATION	ON
A1.	Subject ID	
SEC	TION B: RENAL FAILURE EVEN	T INFORMATION
B1.	Adverse Event (record diagnosis)	
		<b>V</b>
	a. Adverse Event (MedDRA category)	
		(If not found enter -6)
B2.	a. Date of Onset	
	b. Time of Onset	
В3.	Assessment Date	
B4.	Intensity/Grade of this event::	© Mild/Grade 1
B5.	Relationship to RBC transfusion	<ul> <li>Moderate/Grade 2</li> <li>Severe/Grade 3</li> <li>Life threatening/Grade 4</li> <li>Death/Grade 5</li> <li>Not related</li> <li>Possibly related</li> <li>Probably related</li> <li>Related</li> </ul>
	Has the subject experienced a	ny of the following:
a.	Increase in creatinine to 3x baseline?	○ Yes ○ No (B6b)
	<ol> <li>Baseline creatinine level (mg/dL)</li> </ol>	
	2. Date of baseline creatinine level assessment	
	3. Time of baseline creatinine level assessment	
	4. Peak creatinine level (mg/dL)	
	5. Date of peak creatinine level assessment	
	6. Time of peak creatinine level assessment	
b.	Absolute creatinine greater than or equal to 4.0 mg/dL with acute rise of >0.5 mg/dL?	○ Yes ○ No(B6c)
	1. Creatinine level (mg/dL)	

	2. Date of creatinine assessment			
	3. Time of creatinine assessment			
	4. Prior creatinine level (mg/dL)			
	5. Date of prior creatinine assessment			
	6. Time of prior creatinine assessment			
C.	Dialysis?	○ Ye	es 🕜 No	o (B6d)
	1. Date dialysis initiated			
d.	Hemofiltration?	Yes	s 🕜 No	(B7a)
	1. Date hemofiltration initiated			
В7.	What was the treatment for the	nis eve	nt? Ans	swer all questions.
		Yes	No	
a.	None (Observation)	0	0	
b.	Procedure (If yes, discuss procedure in narrative)	0	0	
C.	Medication (If yes, discuss medication in narrative)	0	0	
d.	Other (If yes, discuss other in narrative)	0	0	
	1. Specify other			
B8.	Outcome	O Pag	solved v	without sequalea
				with sequelae
		<ul><li>Not</li></ul>	resolv	ed (B9a)
		Not	resolv	ed at death (B9a)
a.	Date event resolved			
В9.	What, if any, the following ser	ious c	riteria v	were met with this event? Answer all questions.
		Yes	No	
a.	Life-threatening	0	0	
b.	Requires hospitalization or prolongation of existing hospitalization	O	0	
C.	Results in a persistent or significant disability/incapacitation	0	0	
d.	Medically important event	0	$\circ$	
e.	Results in a congenital anomaly/birth defect	0	0	
f.	Results in death	0	0	
	1. Date of death			
B10.	Was the subject withdrawn from the study due to this	○ Yes	s 🔿 No	

B11. Brief description of clinical presentation, treatment and evolution of event, and any other assessments (e.g. laboratory data) which help explain the event and have not been recorded elsewhere on this form. If the outcome of the SAE was death, write cause of death.	
DONE	

RE82: Renal Event Form Version: C

		V 6/1 3/16/11.					
SEC	SECTION A: GENERAL INFORMATION						
A1.	Subject ID						
CEO	TION D. DENIAL FALLUDE EV	VENT INFORMATION					
	TION B: RENAL FAILURE EV Adverse Event (record						
DI.	diagnosis)						
	a. Adverse Event (MedDRA category)						
		(If not found enter -6)					
B2.	a. Date of Onset						
	b. Time of Onset						
B3.	Assessment/Report Date						
B4.	Intensity/Grade of this event:	<ul> <li>Mild/Grade 1</li> <li>Moderate/Grade 2</li> <li>Severe/Grade 3</li> <li>Life threatening/Grade 4</li> <li>Death/Grade 5</li> </ul>					
B5.	Relationship to RBC transfusion	<ul><li>Not related</li><li>Possibly related</li><li>Probably related</li><li>Related</li></ul>					
	Has the subject experience						
a.	Increase in creatinine to 3x baseline?	○ Yes ○ No (B6b)					
	1. Baseline creatinine level (mg/dL)						
	2. Date of baseline creatinine level assessment						
	3. Time of baseline creatinine level assessment						
	4. Peak creatinine level (mg/dL)						
	5. Date of peak creatinine level assessment						
	6. Time of peak creatinine level assessment						
b.	Absolute creatinine greater than or equal to 4.0 mg/dL with acute rise of >0.5 mg/dL?	○ Yes ○ No(B6c)					

	1. Creatinine level (mg/dL)	
	2. Date of creatinine assessment	
	3. Time of creatinine assessment	
	4. Prior creatinine level (mg/dL)	
	5. Date of prior creatinine assessment	
	6. Time of prior creatinine assessment	
C.	Dialysis?	C Yes C No (B6d)
	1. Date dialysis initiated	
d.	Hemofiltration?	C Yes C No (B7a)
	1. Date hemofiltration initiated	
B7.	What was the treatment for	r this event? Answer all questions.
		Yes No
	None (Observation)	O
b.	Procedure (If yes, discuss procedure in narrative)	O O
C.	Medication (If yes, discuss medication in narrative)	ОО
d.	Other (If yes, discuss other in narrative)	O
	1. Specify other	
DO	Outcome	
B8.	Outcome	Resolved without sequalea     Resolved with sequelae
		Not resolved (B9a)
		Not resolved at death (B9a)
a.	Date event resolved	
B9.	What, if any, the following	serious criteria were met with this event? Answer all questions.
		Yes No
a.	Life-threatening	O
b.	Requires hospitalization or prolongation of existing hospitalization	O O
C.	Results in a persistent or significant disability/incapacitation	0 0
d.	Important Medical Event Any adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other serious adverse event criteria (B9a-c, e-f).	

e. Results in a congenital anomaly/birth defect	0	0
f. Results in death	0	С
1. Date of death		
B10. What, if any, of the following Answer all questions.	ng une	expected and unanticipated event criteria were met with this event?
·	Yes	No
a. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol, consent form, and other study documents, and (b) the characteristics of the subject population being studied and the expected natural progression of any underlying disease, disorder, or condition.	О	
<ul> <li>Related or possibly related to a subject's participation in the research</li> </ul>	0	С
c. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.	C	
B11. Was the subject withdrawn from the study due to this event?	○ Ye	es C No
B12. Brief description of clinical presentation, treatment and evolution of event, and any other assessments (e.g. laboratory data) which help explain the event and have not been recorded elsewhere on this form. If the outcome of the SAE was death, write cause of death.		
DONE	,	_

RE83: Other Adverse Event Form  Version: A						
SECTION A: GENERAL INFORMATI	ION					
A1. Subject ID						
SECTION B: ADVERSE EVENT INFO	ORMATION					
B1. Adverse Event (record diagnosis)						
,						
a. Adverse Event (MedDRA						
category)						
a. Date of Onset						
b. Time of Onset						
B3. Assessment Date						
B4. Intensity	○ Mild					
	C Moderate					
B5. Relationship to RBC	C Severe  Not related					
transfusion	C Possibly related					
	© Probably related © Related					
B6. What was the treatment for the						
	Yes No					
a. None (Observation)	• •					
<ul><li>b. Procedure (If yes, discuss procedure in narrative)</li></ul>	o o					
<ul> <li>c. Medication (If yes, discuss medication in narrative)</li> </ul>	O O					
d. Other (If yes, discuss other in narrative)	O O					
1. Specify other						
B7. Outcome	© Resolved without sequelae					
	C Resolved with sequelae					
	C Not resolved (B7a) C Not resolved at death (B7a)					
a. Date of resolution						
B8. What, if any, of the following	serious criteria were met with this event? Answer all questions.					

		Yes	No
a.	Life-threatening	0	O
b.	Requires hospitalization or prolongation of existing hospitalization	0	O
C.	Results in a persistent or significant disability/incapacitation	0	O
d.	Medically important event	0	O
e.	Results in congenital anomaly/birth defect	0	O
f.	Results in death	0	O
	1. Date of death		
B9.	Was the subject withdrawn from the study due to this event?	© Ye	es C No
B10	Brief description of clinical presentation, treatment and evolution of event, and any other assessments (e.g. laboratory data) which help explain the event and have not been recorded elsewhere on this form. If the outcome of the SAE was death, write cause of death.		
DO	NE		_

	RE83: Other Adverse Event Form  Version: B					
_						
SECTION A: GENERAL INFORMAT	FTON					
SECTION A. GENERAL INFORMAT						
A1. Subject ID						
SECTION B: ADVERSE EVENT INF	FORMATION					
B1. Adverse Event (record						
diagnosis)						
	<u></u>					
<ul><li>a. Adverse Event (MedDRA category)</li></ul>						
	▼					
B2 a. Date of Onset	(If not found enter -6)					
b. Time of Onset						
B3. Assessment Date						
B4. Intensity/Grade of this event:	Mild/Grade 1					
	O Moderate/Grade 2					
	<ul><li>Severe/Grade 3</li><li>Life threatening/Grade 4</li></ul>					
	O Death/Grade 5					
B5. Relationship to RBC transfusion	○ Not related					
Crunsiusion	© Possibly related					
	<ul><li>Probably related</li><li>Related</li></ul>					
B6. What was the treatment for	this event? Answer all questions.					
	Yes No					
a. None (Observation)	• •					
<ul> <li>b. Procedure (If yes, discuss procedure in narrative)</li> </ul>	o o					
<ul> <li>c. Medication (If yes, discuss medication in narrative)</li> </ul>	0 0					
<ul> <li>d. Other (If yes, discuss other in narrative)</li> </ul>	0 0					
1. Specify other						
B7. Outcome	© Resolved without sequelae					
	C Resolved without sequelae					
	○ Not resolved (B7a)					
	○ Not resolved at death (B7a)					

a. Date	of resolution			
B8. What	t, if any, of the following s	erious	criter	ia were met with this event? Answer all questions.
		Yes	No	
a. Life-t	hreatening	0	0	
prolo	ires hospitalization or ngation of existing italization	0	0	
signif	lts in a persistent or ficant illity/incapacitation	0	0	
d. Medic	cally important event	0	O	
e. Resul anom	lts in congenital naly/birth defect	0	O	
f. Resul	lts in death	0	0	
1. Da	ate of death			
B9. Was t from event	the subject withdrawn the study due to this t?	© Yes	s 🔿 No	
prese evolu other labor expla not b on th the S	description of clinical entation, treatment and altion of event, and any assessments (e.g. atory data) which help in the event and have seen recorded elsewhere is form. If the outcome of AE was death, write e of death.			
DONE				<u>u</u>

RE83: Other Adverse Event Form Version: C

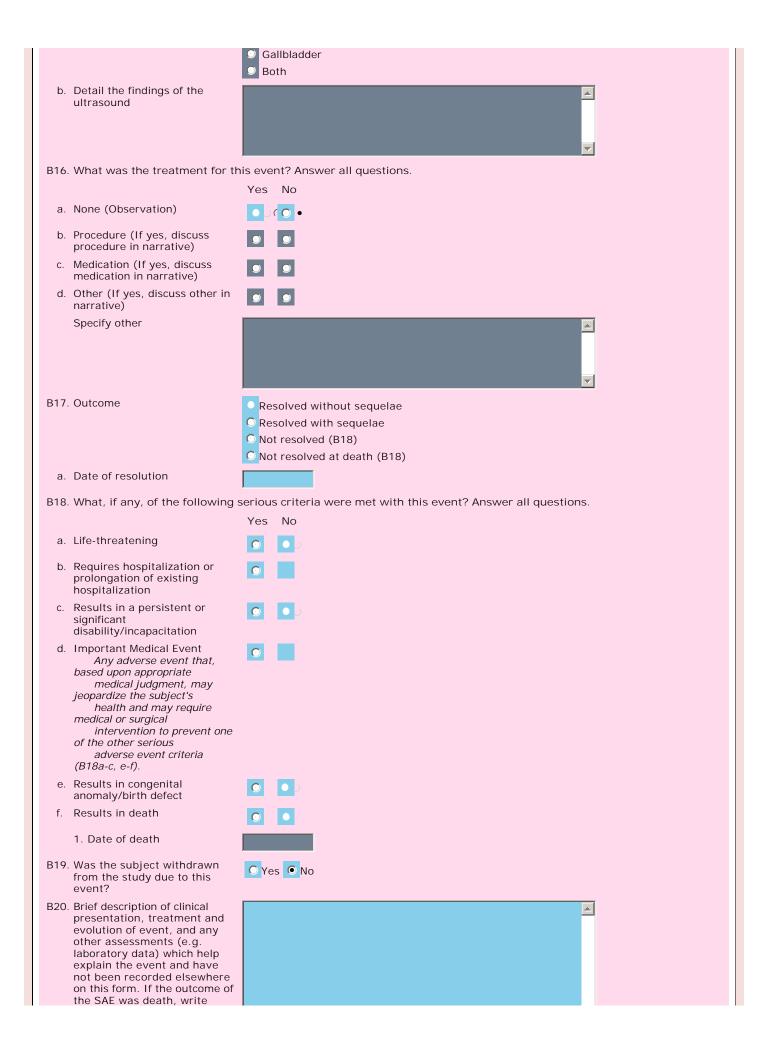
SECTI	ION A: CENEDAL INFORMA	ATION.				
SECTION A: GENERAL INFORMATION						
A1. S	subject ID					
		<del></del>				
SECTI	ION B: ADVERSE EVENT IN	IFORMATION				
	Adverse Event (record diagnosis)		4			
· ·	aragriosis)					
		_				
		]	<u> </u>			
	a. Adverse Event (MedDRA category)		7			
	3,		Z			
		(If not found enter -6)	_			
B2 a	a. Date of Onset					
b	o. Time of Onset					
B3. A	Assessment/Report Date					
	ntensity/Grade of this	C Mild/Grade 1				
е	event:	O Moderate/Grade 2				
		Severe/Grade 3				
		C Life threatening/Grade 4 C Death/Grade 5				
R5 R	Relationship to RBC					
t	ransfusion	<ul><li>Not related</li><li>Possibly related</li></ul>				
		C Probably related				
		C Related				
B6. V	What was the treatment for	this event? Answer all questions.				
		Yes No				
a. N	None (Observation)	O O				
b. P	Procedure (If yes, discuss procedure in narrative)	0 0				
c. N	Medication (If yes, discuss medication in narrative)	0 0				
	Other (If yes, discuss other narrative)	· •				
1	I. Specify other	1	3			
		_				
			4			
B7. C	Dutcome	C Resolved without sequelae				
		C Resolved with sequelae C Not resolved (B8a)				
		Not resulved (boa)				

	○ No	t resolved at death (B8a)
a. Date of resolution		
B8. What, if any, of the follow	ing seri	ious criteria were met with this event? Answer all questions.
	Yes	No
a. Life-threatening	0	O
<ul> <li>Requires hospitalization or prolongation of existing hospitalization</li> </ul>	0	•
<ul> <li>c. Results in a persistent or significant disability/incapacitation</li> </ul>	0	•
d. Important Medical Event Any adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other serious adverse event criteria (B8a-c, e-f).	C	
e. Results in congenital anomaly/birth defect	0	0
f. Results in death	0	С
1. Date of death		
B9. What, if any, of the followi Answer all questions.	ng une: Yes	xpected and unanticipated event criteria were met with this event?  No
a. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol, consent form, and other study documents, and (b) the characteristics of the subject population being studied and the expected natural progression of any underlying disease, disorder, or condition.	C	
<ul> <li>Related or possibly related to a subject's participation in the research</li> </ul>	0	0
c. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.	0	
B10. Was the subject withdrawn from the study due to this event?	O Ye	es O No
B11. Brief description of clinical presentation, treatment and evolution of event, and any other assessments (e.g. laboratory data) which		

help explain the event and have not been recorded elsewhere on this form. If the outcome of the SAE was death, write cause of death.

	RE84: Abnormal Lab Adverse Event Form Version: A						
SEC	TION A: GENERAL INF	ORMATION					
A1.	Subject ID						
SEC	TION B: ADVERSE EVE	ENT INFORM	1ATI ON				
B1.	Adverse Event (record diagnosis)			_			
a.	Adverse Event (MedDR category)			<u> </u>			
B2.	a. Date of Onset	fou	und enter -6)				
	b. Time of Onset						
B3.	Assessment/Report Da	ate 09	/03/211				
B4.	Intensity/Grade of this		Mild/Grade 1 Moderate/Grade 2 Severe/Grade 3 Life threatening/Grade 4 Death/Grade 5				
B5.	Relationship to RBC transfusion	•	Not related Possibly related				
B6.	Which event are you reporting?	•	Hyperkalemia (B7) Hyperphosphatemia (B8) Hypocalcemia (B9) Hyperbilirubinemia (B11)				
B7.	Hyperkalemia			٦			
	A. Potassium Value (mmol/L)	B. Date Dr (mm/dd/y					
B8.	A. Phosphorous Value (mg/dL)	B. Date Dr (mm/dd/y					
RΩ	Hypocalcomia						

	* If you do no hypocalcemia ionized calcium	data enter "-	m values for -1" and enter				
	A. Calcium Value (mg/dL)	* B. Date Dra (mm/dd/yy)					
		, 333					
		,					
B10. I	onized calcium						
	**If you do no data enter "-1		ed calcium le	vels			
	A. Ionized Calcium Value* (mmol/L)	B. Date Dra					
B11. F	Hyperbilirubinemia	a					
	A. Date Drawn (mm/dd/yyyy)	B. Time Dra (24 hour clo		ue	ect Bilirubin Value B mg/dL)	E. Indirect ilirubin Value (mg/dL)	
B12. V	Vas an LDH done?	•	Yes No (B13)	)			
	A. LDH Value (U/L)	B. Date Dra (mm/dd/yy)					
	Vas a DAT (Direct A est) done?	Antigloblin	Yes No (B15)	)			
	A.	B.	C.	D.	E.	F.	G.
	DAT Result	Date Drawn (mm/dd/yyyy)	Time Drawn (24 hour clock)	Polyspecific	IgG	C3	Eluate
	<ul><li>Postive</li><li>Negative</li></ul>			<ul><li>Postive</li><li>Negative</li></ul>	<ul><li>Postive</li><li>Negative</li></ul>	<ul><li>Postive</li><li>Negative</li></ul>	Alloantibody     Identified
				Not Done	Not Done	Not Done	No Alloantibody Identified
							Not Done
	L	ansfusion	Yes No (B15)	)			
	A. Result	B. Date Dra					
	<ul><li>Postive</li><li>Negative</li></ul>						
B15. V	Vas an ultrasound ind/or gallbaldder	of the liver performed?	Yes No (B16)	)			
a. I	dentify the organ(s	s) •	Liver				



cause of death.	▼	
DONE		

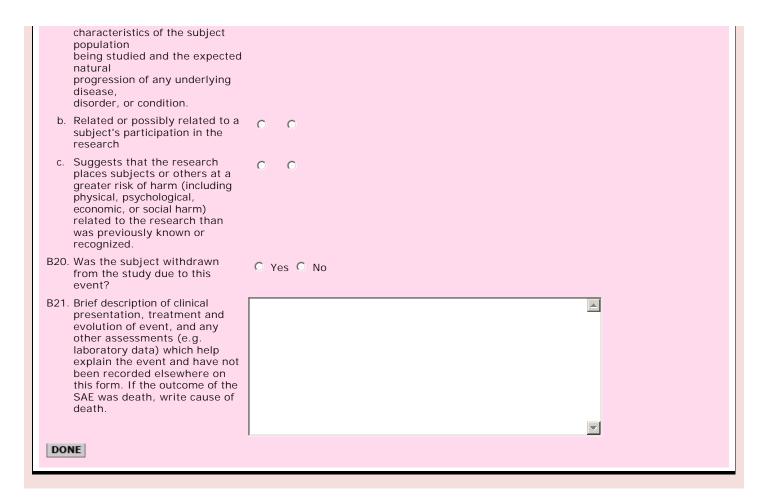
RE84: Abnormal Lab Adverse Event Form Version: B

		Version: I	В					
SECTION A: GENERAL INFORMATION								
A1. Subject ID								
SECTION B: ADVERSE EVENT INF	FORMATION							
B1. Adverse Event (record diagnosis)				<u></u>				
a. Adverse Event (MedDRA category)	not found en	otor (1)		✓ (If				
B2. a. Date of Onset	not round en							
b. Time of Onset								
B3. Assessment/Report Date								
B4. Intensity/Grade of this event:	Mild/Gra	do 1						
B5. Relationship to RBC transfusion	On C Not relat C Possibly C Probably	Grade 3 atening/Grade 4 rade 5 ted related						
B6. Which event are you reportin	C Hyperph C Hypocalc	lemia (B7) iosphatemia (B8) cemia (B9) irubinemia (B11)						
B7. Hyperkalemia								
		C. Time Drawn (24 hour clock)						
B8. Hyperphosphatemia								
		C. Time Drawn (24 hour clock)						
RO Hypocalcomia								

A. Calcium Value (mg/dL)	* B. Date Dra (mm/dd/yy)		C. Time [ <i>(24 hour</i>				
Ionized calcium  **If you do no data enter "-1		ed calci	ium le\	vels			
A. Ionized Calcium Value** (mmol/L)	B. Date Dra		C. Time [ (24 hour				
Hyperbilirubinemia							
A. Date Drawn (mm/dd/yyyy)	B. Time Dra		. Total B Valu (mg/d	ıe l	ect Bilirubin Value mg/dL)	E. Indirect Bilirubin Value (mg/dL)	
Was an LDH done?	O	Yes C	No (B13	3)			
A. LDH Value (U/L)  Was a DAT (Direct A	B. Date Dra (mm/dd/yyy	awn (	C. Time [	Drawn clock)			
A. LDH Value (U/L)  Was a DAT (Direct A	B. Date Dra (mm/dd/yyy	awn (	C. Time I (24 hour	Drawn clock)	E.	F.	G.
A. LDH Value (U/L)  Was a DAT (Direct A Test) done?	B. Date Dra (mm/dd/yy)	Yes O	C. Time I (24 hour  No (B15	Drawn clock)	E. IgG	F. C3	G. Eluate
A. LDH Value (U/L)  Was a DAT (Direct A Test) done?	B. Date Dra (mm/dd/yyy)  Antigloblin  B.  Date Drawn	Yes C  C.  Time D	C. Time I (24 hour  No (B15	Drawn clock)  5)  D.			C Alloantibol Identified C No Alloantibody Identified
A. LDH Value (U/L)  Was a DAT (Direct A Test) done?  A. DAT Result  C Postive	B. Date Dra (mm/dd/yyy  Antigloblin  B.  Date Drawn (mm/dd/yyyy)	Yes C  C.  Time D	No (B15	Drawn clock)  D.  Polyspecific  C Postive C Negative C Not Done	IgG  C Postive Negative	C3 C Postive Negative	C Alloantibol Identified C No Alloantibody Identified
A. LDH Value (U/L)  Was a DAT (Direct A Test) done?  A. DAT Result  C Postive C Negative  Was there a pre-tra	B. Date Dra (mm/dd/yyy  Antigloblin  B.  Date Drawn (mm/dd/yyyy)	Yes C  C.  Time D (24 hour	No (B15	Drawn clock)  D.  Polyspecific  C Postive C Negative C Not Done	IgG  C Postive Negative	C3 C Postive Negative	C Alloantibo

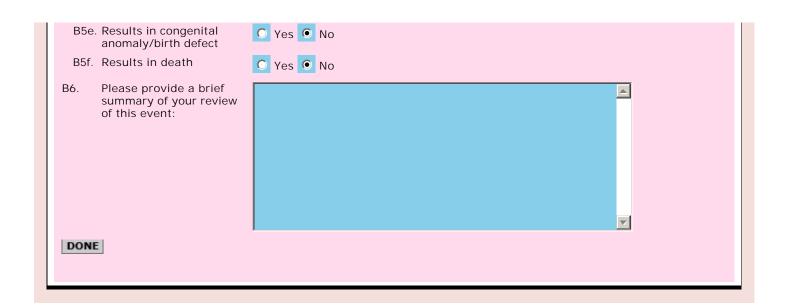
. .

			allbladder	
		О Во	oth	
b.	Detail the findings of the ultrasound			
	uiti asounu			
				$\overline{\mathbf{v}}$
B16.	What was the treatment for this	even	it? Answer all questions.	
		Yes	No	
a.	None (Observation)	0	O	
h	Procedure (If yes, discuss	-		
υ.	procedure in narrative)	0	C	
C.	Medication (If yes, discuss medication in narrative)	0	0	
d.	Other (If yes, discuss other in narrative)	0	0	
	Specify other			
				▼
B17.	Outcome	© Res	solved without sequelae	
		O Res	solved with sequelae	
			t resolved (B18)	
		O No	t resolved at death (B18)	
a.	Date of resolution			
B18.	What, if any, of the following se	rious	criteria were met with this event? Answer all question	S.
		Yes	No	
a.	Life-threatening	0	0	
	Requires hospitalization or prolongation of existing hospitalization	0	•	
C.	Results in a persistent or significant disability/incapacitation	0	•	
d.	Important Medical Event	0	0	
	Any adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other serious adverse event criteria (B18a- c, e-f).			
e.	Results in congenital anomaly/birth defect	0	О	
f.	Results in death	0	О	
	1. Date of death			
B19	What, if any, of the following un	nexpe	cted and unanticipated event criteria were met with th	is event? Answer all
ques	itions.			
		Yes	No	
a.	Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol, consent form, and other study documents, and (b) the	O	•	



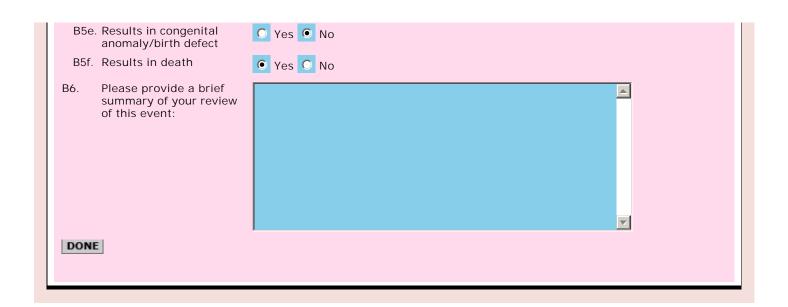
RE88: Transfusion Medicine Event Review Form Version: A

SECT	ION A: GENERAL INFORMA	ATION
A1. St	ubject ID	
A2. D	ate of Review	
A3. In	itials of Reviewer	
SECT	ION B: ADVERSE EVENT IN	JFORMATION
B1.	Adverse Event (as reported on RE80, RE81, RE82, RE83, or RE84)	
B2.	Onset date (from RE80, RE81, RE82, RE83, or RE84)	
a.	Onset time (from RE80, RE81, RE82, RE83, or RE84)	
B3.	In your opinion, what was the intensity/grade of the event?	<ul> <li>Mild/Grade 1</li> <li>Moderate/Grade 2</li> <li>Severe/Grade 3</li> <li>Life Threatening/Grade 4</li> <li>Death/Grade 5</li> </ul>
B4.	In your opinion, what is the relationship of the adverse event to the RBC transfusion?	Not related Possibly related Probably related Related
In yo	ur opinion what, if any, of	the following serious criteria were met with this event? Answer all questions.
B5a	. Life-threatening	Yes No
B5b	. Requires hospitalization or prolongation of existing hospitalization	Yes No
B5c	Results in a persistent or significant disability/incapacitation	Yes No
B5d	. Important Medical Event Any adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other serious adverse event criteria (B5a-c, e-f).	



RE89: Cardiac Surgery Event Review Form Version: A

SECTION A	A: GENERAL INFORMA	ATION
A1. Subject	t ID	
A2. Date of	Review	
A3. Initials	of Reviewer	
SECTION E	B: ADVERSE EVENT IN	NFORMATION
repo	erse Event (as orted on RE80, RE81, 2, RE83, or RE84)	<u>*</u>
	et date (from RE80, 1, RE82, RE83, or 4)	
	et time (from RE80, 1, RE82, RE83, or 4)	0
was	our opinion, what the intensity/grade ne event?	<ul> <li>Mild/Grade 1</li> <li>Moderate/Grade 2</li> <li>Severe/Grade 3</li> <li>Life Threatening/Grade 4</li> <li>Death/Grade 5</li> </ul>
the adve	our opinion, what is relationship of the erse event to the RBC isfusion?	Not related Possibly related Probably related Related
In your op	inion what, if any, of	the following serious criteria were met with this event? Answer all questions.
B5a. Life-	-threatening	• Yes • No
or p	uires hospitalization rolongation of ting hospitalization	Yes No
sign	ults in a persistent or ificant bility/incapacitation	Yes No
that appr may subj med one	ortant Medical Event Any adverse event t, based upon ropriate medical judgment, y jeopardize the iect's health and may require dical or surgical intervention to prevent of the other serious adverse event criteria a-c, e-f).	



RE	90: Unblinding Form Version: A
SECTION A: GENERAL INFORMATION	
CECTION CONTROL ON CON	
A1. Subject ID	
SECTION B: DISCLOSURE OF TREATMENT ARM	
B1. Was the subject told the treatment arm assignment?	○ Yes ○ No
B2. Was a clinical staff member told the treatment arm assignment?	C Yes C No
B3. Number of study staff told the treatment arm	
a. Initials of study staff told the treatment arm	
B4. Reason for disclosure. Answer all questions	
a. SAE	○ Yes ○ No
b. Subject request	C Yes C No
c. Physician request	C Yes C No
d. Error	C Yes C No
e. Other Reason:	C Yes C No (B5)
e1. Specify other reason	
	_
<u> </u>	
B5. Provide a brief description of how and/or why	
disclosure occurred:	A
	▼
B6. Date of disclosure of treatment arm assignment:	
DONE	

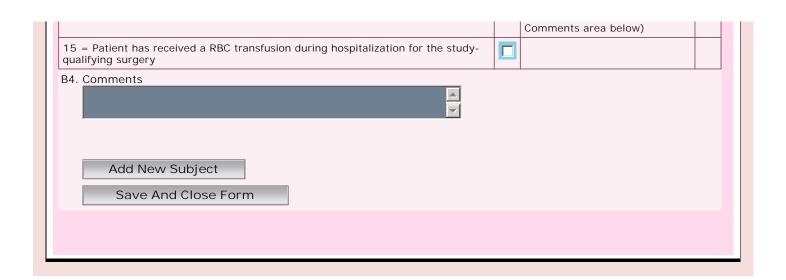
RE91: Protocol Deviation/Unusual Event Form Version: A

SECTIO	N A: GENERAL INFORMATION	
SECTIO	IN A: GENERAL INFORMATION	
A1. Subj	ect ID	
A2. Date	e form completed	(mm/dd/yyyy)
A3. Initi	als of person completing form	
SECTIO	N B: PROTOCOL DEVIATION/ UNUSUAL EV	'ENT
B1.	Is this deviation/event related to an RBC product?	
B2.	Unit ID of product:	
ВЗ. Тур	e of product deviation/event:	
a.	Age of RBC product not in accordance with treatment arm assignment	
b.	Storage medium deviation	
C.	Processing deviation	
d.	Other product deviation/event	
d1.	Specify other event:	
		_
B4.	Date of protocol deviation/unusual event	(mm/dd/yyyy)
B5.	Time of protocol deviation/unusual event	(24-hour clock)
B6.	Describe protocol deviation or unusual event and any action taken:	
В7а.	Code: 1	(DCC use only)
B7b.	Code: 2	(DCC use only)
B7c.	Code: 3	(DCC use only)

DONE

RU00: RECESS Study Screening Log Version: B

SECTION A: GENERAL INFORMATION		
A1. Site ID number		
A2. Screening: Month/Year MM/YYYY		
SECTION B: SCREENING INFORMATION		
B1. Date screened		
B2. Gender Male  Female		
Disposition Codes	Disposition Codes	
1 = TRUST score < 4 Calculated TRUST score  0 0 1 0 2 3	16 = Patient/family refused consent (did not want "old" blood)	
2 = TRUST Score not able to be calculatedinadequate information	17 = Patient/family refused consent (did not want "young" blood)	
3 = Blood bank unable to support patient  Patient's blood type:  A+ B+ AB+ O+  A- B- AB- O-	18 = Patient's physician refused consent (did not want "old" blood)	
4 = Patient enrolled in another competing or conflicting study	19 = Patient's physician refused consent (did not want "young" blood)	
5 = Patient has known transfusion reaction history	20 = Patient/family refused consent for religious reasons	
6 = Patient has known red blood cell antibodies	21 = Patient/family feels overwhelmed	
7 = Patient requires washed products, volume reduced products, or products with additive solution removed	22 = Patient/family wants standard of care	
8 = Patient is expected to have residual cyanosis with O <sub>2</sub> saturation < 90	23 = Patient/family does not want to be a part of research	
9 = Patient has, or is expected to have left ventricular assist device (LVAD) or extracorporeal membrane oxygenation (ECMO) support post-operatively	24 = Patient does not want extra blood draws/testing	
10 = Patient has had Intra-aortic balloon pump (IABP) for cardiogenic shock	25 = Patient/family is concerned about confidentiality	
11 = Patient has Deep Hypothermic Circulatory Arrest (DHCA) planned	26 = Patient unable to provide consent	
12 = Patient has renal dysfunction requiring renal replacement therapies (Hemodialysis (HD), Continuous venovenous hemofiltration (CVVF)) preoperatively	27 = Consent is not in patient's spoken language	
13 = Use of alternative to heparin, e.g. bivalirudin, is planned for this patient	98 = No reason given	
14 = Use of autologous or directed donations is planned for this patient	99 = Other (If selected, please specify other reason in	



RU00: RECESS Study Screening Log Version: C

SECTION A: GENERAL INFORMATION		
A1. Site ID number		
A2. Screening: Month/Year MM/YYYY		
SECTION B: SCREENING INFORMATION		
B1. Date screened		
B2. Gender		
Disposition Codes	Disposition Codes	
1 = TRUST score < 3 Calculated TRUST score  0 1 9 2	16 = Patient/family refused consent (did not want "old" blood)	
2 = TRUST Score not able to be calculatedinadequate information	17 = Patient/family refused consent (did not want "young" blood)	
3 = Blood bank unable to support patient Patient's blood type:  A+ B+ AB+ O+  AB- O-	18 = Patient's physician refused consent (did not want "old" blood)	
4 = Patient enrolled in another competing or conflicting study	19 = Patient's physician refused consent (did not want "young" blood)	
5 = Patient has known transfusion reaction history	20 = Patient/family refused consent for religious reasons	
6 = Patient has known red blood cell antibodies	21 = Patient/family feels overwhelmed	
7 = Patient requires washed products, volume reduced products, or products with additive solution removed	22 = Patient/family wants standard of care	
8 = Patient is expected to have residual cyanosis with ${\rm O_2}$ saturation < 90	23 = Patient/family does not want to be a part of research	
9 = Patient has, or is expected to have left ventricular assist device (LVAD) or extracorporeal membrane oxygenation (ECMO) support post-operatively	24 = Patient does not want extra blood draws/testing	
10 = Patient has had Intra-aortic balloon pump (IABP) for cardiogenic shock	25 = Patient/family is concerned about confidentiality	
11 = Patient has Deep Hypothermic Circulatory Arrest (DHCA) planned	26 = Patient unable to provide consent	
12 = Patient has renal dysfunction requiring renal replacement therapies (Hemodialysis (HD), Continuous venovenous hemofiltration (CVVF)) preoperatively	27 = Consent is not in patient's spoken language	
13 = Use of alternative to heparin, e.g. bivalirudin, is planned for this patient	98 = No reason given	
14 = Use of autologous or directed donations is planned for this patient	99 = Other (If selected, please specify other reason in Comments area below)	
15 = Patient has received a RBC transfusion during hospitalization for the study-qualifying surgery		
B4. Comments		

Add New Subject

Save And Close Form