Transfusion Medicine/Hemostasis Clinical Trials Network

RE01: Consent Confirmation Form
Version: A

SECTION A: GENERAL INFORMATION

A1. Subject ID

SECTION B: CONSENT

B1. Has subject signed consent form? ○ Yes ○ No (END)

B2. Has the subject signed HIPAA authorization? ○ Yes ○ No

B3. Was signed copy of consent given to subject? ○ Yes ○ No

B4. Date consent signed

B5. What is the IRB approval expiration date of consent signed by the subject?

DONE

Transfusion Medicine/Hemostasis Clinical Trials Network

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 patients prior to surgery.

B1. Date of Birth

B2. Gender ○ Male ○ Female

B3. Hemoglobin (g/dL)

B4. Weight (kg)

B5. Elective Surgery ○ Yes ○ No

B6. Serum Creatinine (mg/dL)

B7. Does the subject have a history of cardiac surgery? ○ Yes ○ No

B8. Surgical Task ○ Isolated (single procedure) ○ Non-Isolated

B9. TRUST Score

Parameter	Finding	Points
age of the patient in years	<= 65 years	0
	> 65 years	1
Gender	male	0
	female	1
hemoglobin	>= 13.5 g/dL	0
	< 13.5 g/dL	1
body weight in kilograms	>=77 kilograms	0
	< 77 kilograms	1
elective surgery	yes	0
	no (nonelective)	1
serum creatinine	<= 1.36 mg/dL (120 Âµmol/L)	0
	> 1.36 mg/dL (120 Âµmol/L)	1
history of previous cardiac surgery	no	0
	yes	1
surgical task	isolated	0
	nonisolated (CABG + valve replacement, etc)	1

SECTION C: BLOOD TYPE

C1. ABO Blood Group ○ A ○ B ○ AB ○ O

C2. Rh Type	○ 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?	○ Yes (Ineligible) ○ No
E2. Is the subject having minimally invasive surgery?	○ Yes (Ineligible) ○ No
E3. Does the subject have a known transfusion reaction history?	○ Yes (Ineligible) ○ 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?	○ Yes (Ineligible) ○ No
E6. Is the subject expected to have residual cyanosis with oxygenation saturation < 90?	○ Yes (Ineligible) ○ 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).	○ Yes (Ineligible) ○ No
E9. Does the subject have a planned Deep Hypothermic Circulatory Arrest (DHCA)?	○ Yes (Ineligible) ○ No
E10. Does the subject have renal dysfunction requiring renal replacement therapies (hemodialysis (HD), continuous venovenous hemofiltration (CVVH)) pre-operatively?	○ Yes (Ineligible) ○ 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?	○ Yes (Ineligible) ○ 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 STRATIFICATION

G1. Is the subject currently in the ICU at the time of randomization in the RECESS study?	○ Yes ○ 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	○ Red Blood Cell units stored â ‰ ¤ 10 days ○ RBC stored units â ‰ ¥ 21 days ○ Both Red Blood Cell units stored â ‰ ¤ 10 days AND â ‰ ¥ 21 days
b. Were more than 6 units requested for this subject?	○ Yes ○ No
b1. Number of units requested	

DONE

Transfusion Medicine/Hemostasis Clinical Trials Network

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 patients prior to surgery.

B1. Date of Birth

B2. Gender
- Male
- Female

B3. Hemoglobin (g/dL)

B4. Weight (kg)

B5. Elective Surgery
- Yes
- No

B6. Serum Creatinine (mg/dL)

B7. Does the subject have a history of cardiac surgery?
- Yes
- No

B8. Surgical Task
- Isolated (single procedure)
- Non-Isolated

B9. Minimum TRUST Score

Parameter	Finding	Points
age of the patient in years	<= 65 years	0
	> 65 years	1
Gender	male	0
	female	1
hemoglobin	>= 13.5 g/dL	0
	< 13.5 g/dL	1
body weight in kilograms	>=77 kilograms	0
	< 77 kilograms	1
elective surgery	yes	0
	no (nonelective)	1
serum creatinine	<= 1.36 mg/dL (120 µmol/L)	0
	> 1.36 mg/dL (120 µmol/L)	1
history of previous cardiac surgery	no	0
	yes	1
surgical task	isolated	0
	non-isolated (CABG + valve replacement, etc)	1

SECTION C: BLOOD TYPE

C1. ABO Blood Group
- A
- B

	○ AB ○ O
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?	○ Yes ○ No (Ineligible)

SECTION E: EXCLUSION CRITERIA

E1. Did the subject refuse blood products?	○ Yes (Ineligible) ○ No
E2. Is the subject having minimally invasive surgery?	○ Yes (Ineligible) ○ No
E3. Does the subject have a known transfusion reaction history?	○ Yes (Ineligible) ○ 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?	○ Yes (Ineligible) ○ No
E6. Is the subject expected to have residual cyanosis with oxygenation saturation < 90?	○ Yes (Ineligible) ○ 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).	○ Yes (Ineligible) ○ No
E9. Does the subject have a planned Deep Hypothermic Circulatory Arrest (DHCA)?	○ Yes (Ineligible) ○ No
E10. Does the subject have renal dysfunction requiring renal replacement therapies (hemodialysis (HD), continuous venovenous hemofiltration (CVVH)) pre-operatively?	○ Yes (Ineligible) ○ 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?	○ Yes (Ineligible) ○ 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 STRATIFICATION

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 requested for this subject?	
G3. a. Date Transfusion Service contacted for RBC unit availability	
b. Time Transfusion Service contacted for RBC unit 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 in the current inventory to meet the crossmatch request?

- ○ Yes (End of Form)
- ○ No

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

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

DONE

Transfusion Medicine/Hemostasis Clinical Trials Network

RE02: Confirmation of Eligibility and Randomization Form
Version: C

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 patients prior to surgery.

B1. Date of Birth

B2. Gender
- Male
- Female

B3. Hemoglobin (g/dL)

B4. Weight (kg)

B5. Elective Surgery
- Yes
- No

B6. Serum Creatinine (mg/dL)

B7. Does the subject have a history of cardiac surgery?
- Yes
- No

B8. Surgical Task
- Isolated (single procedure)
- Non-Isolated

B9. Minimum TRUST Score

Parameter	Finding	Points
age of the patient in years	<= 65 years	0
	> 65 years	1
Gender	male	0
	female	1
hemoglobin	>= 13.5 g/dL	0
	< 13.5 g/dL	1
body weight in kilograms	>=77 kilograms	0
	< 77 kilograms	1
elective surgery	yes	0
	no (nonelective)	1
serum creatinine	<= 1.36 mg/dL (120 µmol/L)	0
	> 1.36 mg/dL (120 µmol/L)	1
history of previous cardiac surgery	no	0
	yes	1
surgical task	isolated	0
	non-isolated (CABG + valve replacement, etc)	1

SECTION C: BLOOD TYPE

C1. ABO Blood Group
- A
- B

	○ AB ○ O
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?	○ Yes ○ No (Ineligible)

SECTION E: EXCLUSION CRITERIA

E1. Did the subject refuse blood products?	○ Yes (Ineligible) ○ No
E2. Is the subject having minimally invasive surgery?	○ Yes (Ineligible) ○ No
E3. Does the subject have a known transfusion reaction history?	○ Yes (Ineligible) ○ 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?	○ Yes (Ineligible) ○ 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?	○ Yes (Ineligible) ○ 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).	○ Yes (Ineligible) ○ 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?	○ Yes (Ineligible) ○ 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?	○ Yes (Ineligible) ○ No
E13. 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 STRATIFICATION

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 requested for this subject?	
G3. a. Date Transfusion Service contacted for RBC unit availability	
b. Time Transfusion Service contacted for RBC unit 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 in the current inventory to meet the crossmatch request?	○ Yes (End of Form) ○ No

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

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

DONE

Transfusion Medicine/Hemostasis Clinical Trials Network

RE04: Demographics and Medical History Form
Version: A

SECTION A: GENERAL INFORMATION

A1. Subject ID

SECTION B: DEMOGRAPHICS

B1. Ethnicity

- ○ Hispanic or Latino
- ○ Not Hispanic or Latino
- ○ Refused
- ○ Not Obtained/Unknown

B2.	Race	Yes	No	Refused	Not Obtained/ Unknown
	a. Native American	○	○	○	○
	b. Asian	○	○	○	○
	c. Black, African origin/African American	○	○	○	○
	d. Hawaiian or Pacific Islander	○	○	○	○
	e. White	○	○	○	○
	f. Other	○	○	○	○
	f1. Other, specify				

B3. Height (cm)

SECTION C: MEDICAL HISTORY

C1. Does the subject currently carry a diagnosis of hypertension? ○ Yes ○ No (C2)

a. Currently treated? ○ Yes ○ No

C2. Does the subject currently carry a diagnosis of diabetes? ○ Yes ○ No (C3)

a. Treatment

- ○ Oral agent
- ○ Insulin
- ○ Behavorial

C3. Does the subject have a history of smoking? ○ Yes ○ No (C4)

a. Is the subject a current smoker? (within the last 30 days) ○ Yes ○ No

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

C7. 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?
- ○ Yes
- ○ No (C10)
- ○ Unknown (C10)

a. Date of most recent transfusion prior to this admission

b. Was the subject ever transfused at this institution? ○ Yes ○ No (C10)

b1. Date of most recent transfusion at this institution

Enter the most recent left ventricular ejection fraction prior to date of surgery, or during surgery but prior to CPB.

C10. Date of left ventricular ejection fraction assessment

a. Time of left ventricular ejection fraction assessment

C11. Was a numeric value obtained for the left ventricular ejection fraction?
- ○ Yes
- ○ No (C11b)

a. Left ventricular ejection fraction (%)

b. Left ventricular ejection fraction (category)
- ○ Normal
- ○ Moderately depressed
- ○ Severly depressed
- ○ Other

DONE

Transfusion Medicine/Hemostasis Clinical Trials Network

RE05: Adverse Event Checklist
Version: A

SECTION A: GENERAL INFORMATION

A1. Subject ID

A2. Date of Assessment

SECTION B: CLINICAL EVENTS

B1. Did the subject experience any of the following events on the assessment date? ○ Yes ○ No (END)

B2. **Myocardial Infarction Event/Cardiac ischemia:** ○ Yes ○ No
- Grade 2: Asymptomatic and cardiac enzymes minimally abnormal and no evidence of ischemic ECG changes
- Grade 3: Severe symptoms; cardiac enzymes abnormal; hemodynamically stable; ECG changes consistent with infarction
- Grade 4: Life-threatening consequences;hemodynamically unstable

B3. **Pulmonary Embolism:** ○ Yes ○ No
a blockage of an artery in the lungs by fat, air, a blood clot, or tumor cells

B4. **Stroke Event:** ○ Yes ○ No
characterized by sudden loss of sensory function due to an intracranial vascular event

B5. **Renal Event includes any of the following:** ○ Yes ○ No
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

B6. **Infection/Sepsis Event defined as:** ○ Yes ○ No
- Grade 2: localized, local intervention indicated
- 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)

B7. **Ventricular tachycardia:** ○ Yes ○ No
characterized by a dysrhythmia with a heart rate greater then 100 beats per minute that originates distal to the bundle of His

B8. **Ventricular fibrillation:** ○ Yes ○ No
characterized by a dysrhythmia without discernible QRS complexes due to rapid repetitive excitation of myocardial fibers without coordinated contraction of the ventricles

B9. **TACO (Transfusion-associated congestive heart failure/transfusion-associated circulatory overload):** ○ Yes ○ No
characterized by increased blood pressure, tachycardia, setting of rapid or massive transfusion, and a positive fluid balance

B10. **TRALI (Transfusion-related acute lung injury):** ○ Yes ○ No
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

B11. **Anaphylaxis:** ○ Yes ○ No
characterized by a rapid onset of hypotension (often severe) and dypsnea; erythematous confluent rash; and no evidence of

pulmonary edema

B12. **Graft vs Host Disease:** ○ Yes ○ No
characterized by an erythematous rash, diarrhea, and liver function test abnormalities. Fever may or may not be present. Marrow aplasia and pancytopenia may also occur

Do not report events listed below (B13-B29) separately if reported as part of one of the events listed above.

B13. **Allergic Reaction:** ○ Yes ○ No
characterized by an adverse local or general response from exposure to an allergen
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.

B14. **Sinus Bradycardia:** ○ Yes ○ No
characterized by a dysrhythmia with a heart rate less then 60 beats per minute that originates in the sinus node
Grade 2: symptomatic, medical intervention indicated
Grade 3: severe, medically significant, medical intervention indicated
Grade 4: life-threatening consequences; urgent intervention indicated

B15. **Sinus Tachycardia:** ○ Yes ○ No
characterized by a dysrhythmia with a heart rate greater then 100 beats per minute that originates in the sinus node
Grade 2: symptomatic, non-urgent medical intervention indicated
Grade 3: urgent medical intervention indicated

B16. **Hypertension:** ○ Yes ○ No
characterized by pathological increase in blood pressure; a repeated elevation in the blood pressure exceeding 140/90 mmHg

B17. **Hypotension:** ○ Yes ○ No
characterized by a blood pressure that is below the normal expected for an individual in a given environment
Grade 2: Non-urgent medical intervention indicated
Grade 3: Medical intervention or hospitalization indicated
Grade 4: Life threatening and urgent intervention indicated

B18. **Dyspnea:** ○ Yes ○ No
characterized by an uncomfortable sensation of difficulty breathing
Grade 2: shortness of breath with minimal exertion; limiting instrumental ADL
Grade 3: shortness of breath at rest; limiting self care ADL
Grade 4: life-threatening consequences; urgent intervention indicated

B19. **Hypoxia:** ○ Yes ○ No
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:** ○ Yes ○ No
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

indicated; limiting instrumental ADL

Grade 3: Severe respiratory symptoms limiting self care ADL; oxygen therapy or hospitalization indicated

Grade 4: Life-threatening consequences; urgent intervention indicated

B21. **Cough:** ○ Yes ○ No
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. **Fever:** ○ Yes ○ No
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

B23. **Chills:** ○ Yes ○ No
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. **Hemolysis:** ○ Yes ○ No
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. **Hyperkalemia:** ○ Yes ○ No
High serum potassium

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. **Hyperphosphatemia:** ○ Yes ○ No
abnormally high levels of phosphate in the blood

B27. **Hypocalcemia:** ○ Yes ○ No
Low serum calcium

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. **Hyperbilirubinemia:** ○ Yes ○ No
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:** ○ Yes ○ No
characterized by laboratory test results that indicate the presence of free hemoglobin in the urine.

B97. Unanticipated problem ○ Yes ○ No

B98. Other event possibly, probably, or definitely related to RBC transfusion? ○ Yes ○ No

B99. Other Serious Adverse Event (SAE)? ○ Yes ○ No

DONE

Transfusion Medicine/Hemostasis Clinical Trials Network

RE07: Pre-Op Measurements Form
Version: A

Temporary Save
Save Reload

SECTION A: GENERAL INFORMATION

A1. Subject ID

A2. Date of planned surgery

SECTION B: LABORATORY DATA

Record the measurement closest to the day of surgery

	Lab	Result	Date Drawn	Time Drawn
B1.	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		
B8.	Troponin I	ng/mL		

SECTION C: HEMODYNAMIC PARAMETERS

Record the measurement closest to the day of surgery

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_2)
- a. Result (%)
- b. Date Obtained
- c. Time Obtained

C4. Systemic oxygen saturation (Pulse Oximeter Result, SpO_2)
- a. Result (%)
- b. Date Obtained
- c. Time Obtained

C5. Venous oxygen saturation (PO_2 venous, SvO_2)
- a. Result (%)
- b. Date Obtained
- c. Time Obtained

C6. Glascow coma score
- a1. Eye Opening Result
  - 4 = Spontaneous eye opening
  - 3 = Eye opening to verbal stimuli
  - 2 = Eye opening to pain
  - 1 = No Response

a2. Best Verbal Response
- 5 = Subject is oriented and converses
- 4 = Subject is disoriented and converses
- 3 = Subject uses inappropriate words
- 2 = Subject makes incomprehensible sounds
- 1 = No response

a3. Best Motor Response
- 6 = Subject obeys command
- 5 = Subject localizes pain
- 4 = Subject has flexion withdrawal
- 3 = Subject has abnormal flexion (decorticate rigidity)
- 2 = Subject has extension (decerebrate rigidity)
- 1 = No response

a4. Total Score

b. Date Obtained

c. Time Obtained

C7. Is the subject currently receiving oxygen? Yes / No (C8a)

a. Oxygen device
- Nasal cannula
- Mask
- Intubated

b. Liters of oxygen received

c. FiO2 (%)

d. Date Obtained

e. Time Obtained

C8. PO_2 Arterial (PaO_2, Oxygen level)

a. Result (mmHg)

b. Date Obtained

c. Time Obtained

C9. Does the subject have a central venous catheter in place? Yes / No (C11)

C10. Central Venous Pressure (CVP)

a. Result (cm of water)

b. Date Obtained

c. Time Obtained

C11. Does the subject have a pulmonary artery/Swan-Ganz catheter in place? Yes / No (C21 or C22)

C12. Systemic Vascular Resistance (SVR)

a. Result (dynes)

b. Date Obtained

c. Time Obtained

C13. Pulmonary Capillary Wedge Pressure (PCWP)

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 ($L/min/m^2$)

b. Date Obtained

c. Time Obtained

C16. Oxygen consumption as reported on machine/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_2)

a. Result (%)

b. Date Obtained

c. Time Obtained

C18. Venous oxygen saturation (SvO_2)

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 gas drawn per standard of care? ○ Yes ○ 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 medications in the 7 days prior to surgery or on the surgery date before bypass? ○ Yes ○ No (END)

		Yes	No
a.	Abiciximab (ReoPro)	○	○
b.	Aprotinin (Trasylol)	○	○
c.	Argatroban	○	○
d.	Aspirin	○	○
e.	Bivalirudin (Angiomax)	○	○
f.	Cilostazol (Pletal)	○	○
g.	Clopidogrel (Plavix)	○	○
h.	Dabigatran	○	○
i.	Desirudin	○	○
j.	Desmopressin (DDAVP, Stimate, Minirin)	○	○
k.	Direct Thrombin Inhibitors	○	○
l.	Epsilon Aminocaproic Acid (Amicar)	○	○
m.	Eptifibatide (Integrilin)	○	○
n.	Factor VIIa (NovoSeven)	○	○
p.	Heparin (unfractionated)	○	○
o.	Heparin (low molecular)	○	○
q.	Hirudin	○	○
r.	Lepirudin	○	○
s.	Melagatran	○	○
t.	Nitric Oxide Gas	○	○
u.	Prasugrel (Effient)	○	○
v.	Prothrombin Complex Concentrates	○	○
w.	Sildenafil (Viagra)	○	○

x.	Steroids	○	○
y.	Ticlopidine (Ticlid)	○	○
z.	Tirofiban (Aggrestat)	○	○
aa.	Tranexamic Acid (Cyklokapron)	○	○
bb.	Warfarin (Coumadin)	○	○
zz.	Other anticoagulant or antiplatelet	○	○
	zz1. Specify other		

DONE

Transfusion Medicine/Hemostasis Clinical Trials Network

TMH – 08: RECESS

Form RE07 – Pre-Op Measurements Worksheet

A1. Subject ID: __ __--__ __ __ __ -- __ __ __ -- __

A2. Date of planned surgery __ __ / __ __ / __ __ __ __ *(mm/dd/yyyy)*

Section B: LABORATORY DATA ***Record the measurement closest to the day of surgery***

Lab	**Result**	**Date Drawn** *(mm/dd/yyyy)*	**Time Drawn** *(24 hour clock)*
B1. Creatinine (mg/dL)	_____	__ __ / __ __ / __ __ __ __	__ __:__ __
B2. Bilirubin (mg/dL)	_____	__ __ / __ __ / __ __ __ __	__ __:__ __
B3. Platelet Count ($x10^9$ 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 PARAMETERS ***Record the measurement closest to the day of surgery***

Parameter		**a. Result**	**b. Date Obtained**	**c. Time Obtained**
C1. Heart Rate (beats per minute)	☐ -1 Not done	_____	__ __ / __ __ / __ __ __ __	__ __:__ __
C2. Blood Pressure (mmHg)	☐ -1 Not done	_____ / _____	__ __ / __ __ / __ __ __ __	__ __:__ __
C3. Arterial Oxygen Saturation (SaO_2) (%)	☐ -1 Not done	_____	__ __ / __ __ / __ __ __ __	__ __:__ __
C4. Systemic Oxygen Saturation (Pulse Oximeter Result, SpO_2) (%)	☐ -1 Not done	_____	__ __ / __ __ / __ __ __ __	__ __:__ __
C5. Venous Oxygen Saturation (PO_2 venous, SvO_2) (%)	☐ -1 Not done	_____	__ __ / __ __ / __ __ __ __	__ __:__ __
C6. Glasgow Coma Score	☐ -1 Not done			
a1. Eye opening result	☐ 4 = Spontaneous eye opening	☐ 3 = Eye opening to verbal stimuli	☐ 2 = Eye opening to pain	☐ 1 = No response
a2. Best verbal response	☐ 5 = Subject is oriented and converses	☐ 4 = Subject is disoriented and converses		
	☐ 3 = Subject uses inappropriate words	☐ 2 = Subject makes incomprehensible sounds	☐ 1 = No response	
a3. Best motor response	☐ 6 = Subject obeys command	☐ 5 = Subject localizes pain	☐ 4 = Subject has flexion withdrawal	
	☐ 3 = Subject has abnormal flexion (decorticate rigidity)	☐ 2 = Subject has extension (decerebrate rigidity)	☐ 1 = No Response	

__ __ - __ __ __ __ - __ __ __ - __

			b. Date Obtained	**c. Time Obtained**
a4. Total Score		_____	__ __ / __ __ / __ __ __ __	___ ___:___ ___
C7. Is the subject currently receiving oxygen?		☐1 Yes	☐2 No **(C8a)**	
a. Oxygen device	☐1 Nasal cannula	☐2 Mask	☐3 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_2 Arterial (PaO_2, Oxygen level) (mmHg)		☐-1 Not done	_____	__ __ / __ __ / __ __ __ __ ___ ___:___ ___
C9. Does the subject have a central venous catheter in place?		☐1 Yes	☐2 No	
Parameter		**a. Result**	**b. Date Obtained**	**c. Time Obtained**
C10. Central Venous Pressure (CVP) (mmHg)		☐-1 Not done	_____	__ __ / __ __ / __ __ __ __ ___ ___:___ ___
C11. Does the subject have a pulmonary artery/Swan-Ganz catheter in place?		☐1 Yes	☐2 No **(C22)**	
Parameter		**a. Result**	**b. Date Obtained**	**c. Time Obtained**
C12. Systemic Vascular Resistance (SVR) (dynes)		☐-1 Not done	_____	__ __ / __ __ / __ __ __ __ ___ ___:___ ___
C13. Pulmonary Capillary Wedge Pressure (PCWP) (mmHg)		☐-1 Not done	_____	__ __ / __ __ / __ __ __ __ ___ ___:___ ___
C14. Cardiac Output (L/min)		☐-1 Not done	_____	__ __ / __ __ / __ __ __ __ ___ ___:___ ___
C15. Cardiac Index (L/min/m^2)		☐-1 Not done	_____	__ __ / __ __ / __ __ __ __ ___ ___:___ ___
C16. Oxygen Consumption as reported on machine/readout (L/min)		☐-1 Not done	_____	__ __ / __ __ / __ __ __ __ ___ ___:___ ___
Components of oxygen consumption calculation: Must be done within 30 minutes of each other.				
Parameter		**a. Result**	**b. Date Obtained**	**c. Time Obtained**
C17. Arterial Oxygen Saturation (SaO2) (%)		☐-1 Not done	_____	__ __ / __ __ / __ __ __ __ ___ ___:___ ___
C18. Venous oxygen saturation (SvO_2) (%)		☐-1 Not done	_____	__ __ / __ __ / __ __ __ __ ___ ___:___ ___
C19. Cardiac Output (L/min)		☐-1 Not done	_____	__ __ / __ __ / __ __ __ __ ___ ___:___ ___
C20. Mean Artery Pressure (mmHg)		☐-1 Not done	_____	__ __ / __ __ / __ __ __ __ ___ ___:___ ___
C21. Did the subject have an arterial blood gas drawn per standard of care?		☐1 Yes	☐2 No	
Parameter		**a. Result**	**b. Date Obtained**	**c. Time Obtained**
C22. Whole Blood Lactic Acid (mmol/L)		☐-1 Not done	_____	__ __ / __ __ / __ __ __ __ ___ ___:___ ___
d. Source of Blood	☐1 Arterial	☐2 Peripheral	☐3 Free Flowing Venous Catheter	

__ __ - __ __ __ __ - __ __ __ - __

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? ☐1 Yes ☐2 No **(END)**

a. Abiciximab (ReoPro)	☐1 Yes	☐2 No	p. Therapeutic Heparin (low molecular)	☐1 Yes	☐2 No
b. Aprotinin (Trasylol)	☐1 Yes	☐2 No	q. Hirudin	☐1 Yes	☐2 No
c. Argatroban	☐1 Yes	☐2 No	r. Lepirudin	☐1 Yes	☐2 No
d. Aspirin	☐1 Yes	☐2 No	s. Melagatran	☐1 Yes	☐2 No
e. Bivalirudin (Angiomax)	☐1 Yes	☐2 No	t. Nitric Oxide Gas	☐1 Yes	☐2 No
f. Cilostazol (Pletal)	☐1 Yes	☐2 No	u. Prasugrel (Effient)	☐1 Yes	☐2 No
g. Clopidogrel (Plavix)	☐1 Yes	☐2 No	v. Prothrombin Complex Concentrates	☐1 Yes	☐2 No
h. Dabigatran	☐1 Yes	☐2 No	w. Sildenafil (Viagra)	☐1 Yes	☐2 No
i. Desirudin	☐1 Yes	☐2 No	x. Steroids	☐1 Yes	☐2 No
j. Desmopressin (DDAVP, Stimate, Minirin)	☐1 Yes	☐2 No	y. Ticlopidine (Ticlid)	☐1 Yes	☐2 No
k. Direct Thrombin Inhibitors	☐1 Yes	☐2 No	z. Tirofiban (Aggrestat)	☐1 Yes	☐2 No
l. Epsilon Aminocaproic Acid (Amicar)	☐1 Yes	☐2 No	aa. Tranexamic Acid (Cyklokapron)	☐1 Yes	☐2 No
m. Eptifibatide (Integrilin)	☐1 Yes	☐2 No	bb. Warfarin (Coumadin)	☐1 Yes	☐2 No
n. Factor VIIa (NovoSeven)	☐1 Yes	☐2 No	zz. Other anticoagulant or antiplatelet	☐1 Yes	☐2 No
o. Therapeutic Heparin (unfractionated)	☐1 Yes	☐2 No	Specify other: _____		

Transfusion Medicine/Hemostasis Clinical Trials Network

TMH – 08: RECESS

Form RE07 – Pre-Op Measurements Worksheet

A1. Subject ID: __ __--__ __ __ __ -- __ __ __ -- __

A2. Date of planned surgery __ __ / __ __ / __ __ __ __ *(mm/dd/yyyy)*

Section B: LABORATORY DATA ***Record the measurement closest to the day of surgery***

Lab	**a. Result**	**b. Date Drawn** *(mm/dd/yyyy)*	**c. Time Drawn** *(24 hour clock)*
B1. Creatinine (mg/dL)	_____	__ __ / __ __ / __ __ __ __	___ ___:___ ___
B2. Bilirubin (mg/dL)	_____	__ __ / __ __ / __ __ __ __	___ ___:___ ___
B3. Platelet Count (x10^9 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 measurement closest to the day of surgery***

General Information

C1. Did the subject have an arterial puncture or any of the following lines in place in the 30 days prior to surgery? ☐1 Yes ☐2 No **(C2)**

C1a. Pulmonary Artery line/Swan-Ganz catheter ☐1 Yes ☐2 No

C1b. Arterial line ☐1 Yes ☐2 No

C1c. Central venous catheter ☐1 Yes ☐2 No

C1d. PICC line ☐1 Yes ☐2 No

C1e. Arterial puncture ☐1 Yes ☐2 No

C2. Did the subject receive supplemental oxygen in the 30 days prior to surgery? ☐1 Yes ☐2 No **(C3)**

C2a. Oxygen device ☐1 Nasal cannula ☐2 Mask ☐3 Intubated

C2b. Liters of oxygen received: _____

C3. *This question intentionally left blank*

Other MODS Measurements		**a. Result**	**b. Date Obtained**	**c. Time Obtained**
C4. Heart Rate (beats per minute)	☐-1 Not done	_____	__ __ / __ __ / __ __ __ __	___ ___:___ ___
C5. Blood Pressure (mmHg)	☐-1 Not done	_____ / _____	__ __ / __ __ / __ __ __ __	___ ___:___ ___
C6. PO_2 Arterial (PaO_2, Oxygen level) (mmHg)	☐-1 Not done	_____	__ __ / __ __ / __ __ __ __	___ ___:___ ___
C7. FiO_2 (%)	☐-1 Not done	_____	__ __ / __ __ / __ __ __ __	___ ___:___ ___

__ __ - __ __ __ __ - __ __ __ - __

Other MODS Measurements continued:		**a. Result**	**b. Date Obtained**	**c. Time Obtained**
C8. Mean Arterial Pressure (mmHg)	☐ -1 Not done	_____	__ __ / __ __ / __ __ __ __	___ ___:___ ___
C9. Central Venous Pressure (CVP) (mmHg)	☐ -1 Not done	_____	__ __ / __ __ / __ __ __ __	___ ___:___ ___
C10. Glasgow Coma Score	☐ -1 Not done			
a1. Eye opening result	☐ 4 = Spontaneous eye opening	☐ 3 = Eye opening to verbal stimuli	☐ 2 = Eye opening to pain	☐ 1 = No response
a2. Best verbal response	☐ 5 = Subject is oriented and converses ☐ 3 = Subject uses inappropriate words	☐ 4 = Subject is disoriented and converses ☐ 2 = Subject makes incomprehensible sounds	☐ 1 = No response	
a3. Best motor response	☐ 6 = Subject obeys command ☐ 3 = Subject has abnormal flexion (decorticate rigidity)	☐ 5 = Subject localizes pain ☐ 2 = Subject has extension (decerebrate rigidity)	☐ 4 = Subject has flexion withdrawal ☐ 1 = No Response	
a4. Total Glasgow Coma Score: _____	**b. Date Obtained:** __ __ / __ __ / __ __ __ __	**c. Time Obtained:** ___ ___:___ ___		
Additional Measurements		**a. Result**	**b. Date Obtained**	**c. Time Obtained**
C11. Whole Blood Lactic Acid (mmol/L)	☐ -1 Not done	_____	__ __ / __ __ / __ __ __ __	___ ___:___ ___
d. Source of Blood	☐ 1 Arterial	☐ 2 Peripheral	☐ 3 Free Flowing Venous Catheter or PICC line	
C12. Arterial Oxygen Saturation (SaO_2) (%)	☐ -1 Not done	_____	__ __ / __ __ / __ __ __ __	___ ___:___ ___
C13. Systemic Oxygen Saturation (Pulse Oximeter Result, SpO_2) (%)	☐ -1 Not done	_____	__ __ / __ __ / __ __ __ __	___ ___:___ ___
C14. Venous Oxygen Saturation (PO_2 venous, SvO_2) (%)	☐ -1 Not done	_____	__ __ / __ __ / __ __ __ __	___ ___:___ ___
C15. Systemic Vascular Resistance (SVR) (dynes)	☐ -1 Not done	_____	__ __ / __ __ / __ __ __ __	___ ___:___ ___
C16. Pulmonary Capillary Wedge Pressure (PCWP) (mmHg)	☐ -1 Not done	_____	__ __ / __ __ / __ __ __ __	___ ___:___ ___
C17. Cardiac Output (L/min)	☐ -1 Not done	_____	__ __ / __ __ / __ __ __ __	___ ___:___ ___
C18. Cardiac Index (L/min/m^2)	☐ -1 Not done	_____	__ __ / __ __ / __ __ __ __	___ ___:___ ___
C19. Oxygen Consumption as reported on machine/readout (L/min)	☐ -1 Not done	_____	__ __ / __ __ / __ __ __ __	___ ___:___ ___
Components of oxygen consumption calculation (Report if no readout available (C19) and done within 30 minutes of each other.)				
C20. Does subject have the 3 components of the oxygen consumption calculation obtained within 30 minutes of each other in 30 days prior to surgery?	☐ 1 Yes	☐ 2 No **(D1)**		
Parameter		**a. Result**	**b. Date Obtained**	**c. Time Obtained**
C21. Arterial Oxygen Saturation (SaO2) (%)	☐ -1 Not done	_____	__ __ / __ __ / __ __ __ __	___ ___:___ ___
C22. Venous oxygen saturation (SvO_2) (%)	☐ -1 Not done	_____	__ __ / __ __ / __ __ __ __	___ ___:___ ___
C23. Cardiac Output (L/min)	☐ -1 Not done	_____	__ __ / __ __ / __ __ __ __	___ ___:___ ___

__ __ - __ __ __ __ - __ __ __ - __

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? ☐1 Yes ☐2 No **(END)**

a. Abiciximab (ReoPro)	☐1 Yes	☐2 No	p. Therapeutic Heparin (low molecular)	☐1 Yes	☐2 No
b. Aprotinin (Trasylol)	☐1 Yes	☐2 No	q. Hirudin	☐1 Yes	☐2 No
c. Argatroban	☐1 Yes	☐2 No	r. Lepirudin	☐1 Yes	☐2 No
d. Aspirin	☐1 Yes	☐2 No	s. Melagatran	☐1 Yes	☐2 No
e. Bivalirudin (Angiomax)	☐1 Yes	☐2 No	t. Nitric Oxide Gas	☐1 Yes	☐2 No
f. Cilostazol (Pletal)	☐1 Yes	☐2 No	u. Prasugrel (Effient)	☐1 Yes	☐2 No
g. Clopidogrel (Plavix)	☐1 Yes	☐2 No	v. Prothrombin Complex Concentrates	☐1 Yes	☐2 No
h. Dabigatran	☐1 Yes	☐2 No	w. Sildenafil (Viagra)	☐1 Yes	☐2 No
i. Desirudin	☐1 Yes	☐2 No	x. Steroids	☐1 Yes	☐2 No
j. Desmopressin (DDAVP, Stimate, Minirin)	☐1 Yes	☐2 No	y. Ticlopidine (Ticlid)	☐1 Yes	☐2 No
k. Direct Thrombin Inhibitors	☐1 Yes	☐2 No	z. Tirofiban (Aggrestat)	☐1 Yes	☐2 No
l. Epsilon Aminocaproic Acid (Amicar)	☐1 Yes	☐2 No	aa. Tranexamic Acid (Cyklokapron)	☐1 Yes	☐2 No
m. Eptifibatide (Integrilin)	☐1 Yes	☐2 No	bb. Warfarin (Coumadin)	☐1 Yes	☐2 No
n. Factor VIIa (NovoSeven)	☐1 Yes	☐2 No	zz. Other anticoagulant or antiplatelet	☐1 Yes	☐2 No
o. Therapeutic Heparin (unfractionated)	☐1 Yes	☐2 No	Specify other: _____		

Transfusion Medicine / Hemostasis Clinical Trials Network

RE07: Pre-Op Measurements Form
Version: D

Temporary Save
Save Reload

SECTION A: GENERAL INFORMATION

A1. Subject ID

A2. Date of planned surgery

SECTION B: LABORATORY DATA

Record the measurement closest to the start time of surgery

	Lab	Result	Date Drawn	Time Drawn
B1.	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 the start time of surgery
General Information:

C1. Did the subject have an arterial puncture or any of the following lines in place in the 30 days prior to surgery? ○ Yes ○ No (C2)

a. Pulmonary Artery line/Swan-Ganz catheter ○ Yes ○ No

b. Arterial line ○ Yes ○ No

c. Central venous catheter ○ Yes ○ No

d. PICC line ○ Yes ○ No

e. Arterial Puncture ○ Yes ○ No

C2. Did the subject receive supplemental oxygen entering the OR? ○ Yes ○ No (C4a)

a. Oxygen device
○ Nasal cannula
○ Mask
○ Intubated

b. Liters of oxygen received

C3. *This question intentionally left blank*

Other MODS Measurements:

C4. Heart Rate

a. Result (beats per minute)

b. Date Obtained

c. Time Obtained

C5. Blood Pressure

a1. Systolic Blood Pressure (mmHg)

a2. Diastolic Blood Pressure (mmHg)

b. Date Obtained

c. Time Obtained

C6. PO_2 Arterial (PaO_2, Oxygen level)

a. Result (mmHg)

b. Date Obtained

c. Time Obtained

C7. FiO_2

a. 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

- ○ Spontaneous eye opening
- ○ Eye opening to verbal stimuli
- ○ Eye opening to pain
- ○ No Response

a2. Best Verbal Response

- ○ Subject is oriented and converses
- ○ Subject is disoriented and converses
- ○ Subject uses inappropriate words
- ○ Subject makes incomprehensible sounds
- ○ No response

a3. Best Motor Response

- ○ Subject obeys command
- ○ Subject localizes pain
- ○ Subject has flexion withdrawal
- ○ Subject has abnormal flexion (decorticate rigidity)
- ○ Subject has extension (decerebrate rigidity)
- ○ No response

a4. Total Score ** See note below*

b. Date Obtained

c. Time Obtained

* All subjects that are sedated during the performing of the GCS measurement should still have the observed scores reported for the individual components of the GCS based on the actual assessment of the subject, but the overall score must be given one of the specific special codes below rather than the sum of the individual component scores.

- Code 88 = Sedated, Expected to Be Normal: had normal neurologic function for age by history before surgery and no catastrophic events to change that status are clinically evident, but currently unable to assess because of sedation.
- Code 99 = Sedated, Not Normal: neurologic function not normal by pre-operative history (prior stroke, tumor or trauma sequelae, cognitively challenged, behavioral disorder, etc.) or intra-operative history, but currently unable to assess because of sedation.

Additional Measurements:

C11. Whole Blood Lactic Acid

a. Result (mmol/L)

b. Date Drawn

c. Time Drawn

d. Source of blood

- ○ Arterial
- ○ Peripheral
- ○ Free Flowing Venous Catheter or PICC line

C12. Arterial Oxygen Saturation (SaO_2)

a. Result (%)

b. Date Obtained

c. Time Obtained

C13. Systemic Oxygen Saturation (Pulse Oximeter Result, SpO_2)

a. Result (%)

b. Date Obtained

c. Time Obtained

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? ○ Yes ○ No (END)

		Yes	No	
a.	Abiciximab (ReoPro)	○	○	

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

DONE

Transfusion Medicine/Hemostasis Clinical Trials Network

RE08: Procedure Data Form
Version: A

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
- Primary median sternotomy
- Repeat median sternotomy
- Thoracotomy
- Other (minimally invasive)

a. Specify other

B2. Coronary Surgery	Yes No
a. Simple Coronary: Single Graft	Yes No
b. Complex Coronary	Yes No
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
a. Aortic Valve Surgery	Yes No
a1. Replacement	Yes No
a2. Repair/Reconstruction	Yes No
a3. Reconstruction with Conduit	Yes No
a4. Conduit replacement	Yes No
b. Mitral Valve Surgery	Yes No
b1. Annuloplasty only	Yes No
b2. Replacement	Yes No
b3. Reconstruction	Yes No
c. Pulmonary Valve Surgery	Yes No
c1. Annuloplasty Only	Yes No
c2. Replacement	Yes No
c3. Reconstruction	Yes No
c4. Valvectomy	Yes No
c5. Conduit placement	Yes No
c6. Conduit replacement	Yes No
d. Tricuspid Valve Surgery	Yes No

d1. Annuloplasty Only	Yes No
d2. Replacement	Yes No
d3. Reconstruction	Yes No
d4. Valvectomy	Yes No
B4. Septal Repair	Yes 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	Yes No
a3. Arch repair	Yes No
a4. Ross	Yes No
a5. Kono	Yes No
b. Pulmonary Artery	Yes No
b1. Main Pulmonary Artery Stenosis	Yes No
b2. Branch stenosis	Yes No
c. Pulmonary Veins	Yes No
c1. Total Anomalous Pulmonary Venous Return	Yes No
c2. Partial Anomalous Pulmonary Venous Return	Yes No
d. Partial Ductus Arteriosus	Yes No
B7. Complex Congenital Surgery	Yes No
a1. Transposition Great Arteries	Yes No
a2. Hypoplastic Left Heart Syndrome	Yes No
a3. Tetrology of Fallot	Yes No
a4. Coronary Triatriatum	Yes No
a5. Atrioventricular Canal	Yes No
a6. Truncus Arteriosus	Yes No
b. Palliative	Yes 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	Yes No
b6. Unidirectional Glenn	Yes No

b7. Bidirectional Glenn — Yes 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

a. Specify surgery/procedure

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? Yes No

a. Type of pump used
- Centrifugal Pump
- Roller Pump

C6. CBP duration (minutes)

C7. Duration of aortic cross clamp (minutes)

C8. Was cell saver used during the procedure? Yes No

a. Volume of cell saver blood administered (mL)

C9. Number of Acute Normovolemic Hemodilution units collected

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? Yes No

		Yes	No	
a.	Abiciximab (ReoPro)			
b.	Aprotinin (Trasylol)			
c.	Argatroban			
d.	Aspirin			
e.	Bivalirudin (Angiomax)			

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

DONE

Transfusion Medicine/Hemostasis Clinical Trials Network

RE08: Procedure Data Form
Version: B

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
- Primary median sternotomy
- Repeat median sternotomy
- Thoracotomy
- Other (minimally invasive)

a. Specify other

B2. Coronary Surgery — Yes / No (B3)
- 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 — Yes / No
  - a2. Repair/Reconstruction — Yes / No
  - a3. Reconstruction with Conduit — Yes / No
  - a4. Conduit replacement — Yes / No
- b. Mitral Valve Surgery — Yes / No (B3c)
  - b1. Annuloplasty only — Yes / No
  - b2. Replacement — Yes / No
  - b3. Reconstruction — Yes / No
- c. Pulmonary Valve Surgery — Yes / No (B3d)
  - c1. Annuloplasty Only — Yes / No
  - c2. Replacement — Yes / No
  - c3. Reconstruction — Yes / No
  - c4. Valvectomy — Yes / No
  - c5. Conduit placement — Yes / No
  - c6. Conduit replacement — Yes / No
- d. Tricuspid Valve Surgery — Yes / No (B4)

d1. Annuloplasty Only	Yes 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	Yes No
c. Patent Foramen Ovale Closure	Yes No
B5. Ventricular Surgery	Yes No (B6)
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 (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	Yes No
c1. Total Anomalous Pulmonary Venous Return	Yes No
c2. Partial Anomalous Pulmonary Venous Return	Yes 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	Yes No
a3. Tetrology of Fallot	Yes No
a4. Coronary Triatriatum	Yes No
a5. Atrioventricular Canal	Yes No
a6. Truncus Arteriosus	Yes No
b. Palliative	Yes No (B8)
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	Yes No
b6. Unidirectional Glenn	Yes No

b7. Bidirectional Glenn ○ Yes ○ 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

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? ○ Yes ○ No (C7)

a. Type of pump used
○ Centrifugal Pump
○ Roller Pump

C6. CBP duration (minutes)

C7. Duration of aortic cross clamp (minutes)

C8. Was cell saver used during the procedure? ○ Yes ○ No (C9)

a. Volume of cell saver blood administered (mL)

C9. Number of Acute Normovolemic Hemodilution units collected *(If ANH units were not collected enter -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? ○ Yes ○ No (END)

		Yes	No	
a.	Abiciximab (ReoPro)	○	○	
b.	Aprotinin (Trasylol)	○	○	
c.	Argatroban	○	○	
d.	Aspirin	○	○	
e.	Bivalirudin (Angiomax)	○	○	

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

DONE

Transfusion Medicine/Hemostasis Clinical Trials Network

RE09: Post-Op/Daily Measurement Form
Version: A

Temporary Save
Save Reload

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.

	Lab	Result	Time Drawn
B1.	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)	
B8.	Troponin	(ng/mL)	

SECTION C: HEMODYNAMIC PARAMETERS

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.

C1. Heart rate
- a. Result (beats per minute)
- b. Time Obtained

C2. Blood pressure
- a1. Systolic Blood Pressure (mmHg)
- a2. Diastolic Blood Pressure (mmHg)
- b. Time Obtained

C3. Arterial oxygen saturation (SaO_2)
- a. Result (%)
- b. Time Obtained

C4. Systemic oxygen saturation (Pulse Oximeter Result, SpO_2)
- a. Result (%)
- b. Time Obtained

C5. Venous oxygen saturation (PO_2 venous, SvO_2)
- a. Result (%)
- b. Time Obtained

C6. Glascow Coma Score

a1. Eye Opening Result
- 4 =Spontaneous eye opening
- 3=Eye opening to verbal stimuli
- 2 =Eye opening to pain
- 1 =No Response

a2. Best Verbal Response
- 5 =Subject is oriented and converses
- 4 =Subject is disoriented and converses
- 3 =Subject uses inappropriate words
- 2 =Subject makes incomprehensible sounds
- 1 =No response

a3. Best Motor Response
- 6 =Subject obeys command
- 5 =Subject localizes pain
- 4 =Subject has flexion withdrawal
- 3 =Subject has abnormal flexion (decorticate rigidity)
- 2 =Subject has extension (decerebrate rigidity)
- 1 =No response

a4. Total Score

b. Time Obtained

C7. Is the subject currently receiving oxygen? ○ Yes ○ No (C8a)

a. Oxygen device
- ○ Nasal cannula
- ○ Mask
- ○ Intubated

b. Liters of oxygen received

c. FiO2 (%)

d. Time Obtained

C8. PO_2 Arterial (PaO_2, Oxygen level)

a. Result (mmHg)

b. Time Obtained

C9. Does the subject have a central venous catheter in place? ○ Yes ○ No (C11)

C10. Central Venous Pressure (CVP)

a. Result (cm of water)

b. Time Obtained

C11. Does the subject have a pulmonary artery/Swan-Ganz catheter in place? ○ Yes ○ No(C21or C22)

C12. Systemic Vascular Resistance (SVR)

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)

b. Time Obtained

Components of oxygen consumption calculation: Must be done within 30 minutes of one another.

C17. Arterial oxygen saturation (SaO_2)

a. Result (%)

b. Time Obtained

C18. Venous oxygen saturation (SvO_2)

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? ○ Yes ○ No (D1)

C22. Whole blood lactic acid

a. Result (mmol/L)

b. Time Drawn

SECTION D: MEDICATION CHECKLIST

D1. Please indicate if the subject received any of the following medications on the date of assessment. ○ Yes ○ No (END)

		Yes	No
a.	Abiciximab (ReoPro)	○	○
b.	Aprotinin (Trasylol)	○	○

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

DONE

Transfusion Medicine/Hemostasis Clinical Trials Network

RE09: Post-Op/Daily Measurement Form
Version: C

Temporary Save
Save Reload

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.

	Lab	Result	Time Drawn
B1.	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)	
B8.	Troponin-I	(ng/mL)	

SECTION C: HEMODYNAMIC PARAMETERS

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.

C1. Heart rate

a. Result (beats per minute)

b. Time Obtained

C2. Blood pressure

a1. Systolic Blood Pressure (mmHg)

a2. Diastolic Blood Pressure (mmHg)

b. Time Obtained

C3. Arterial oxygen saturation (SaO_2)

a. Result (%)

b. Time Obtained

C4. Systemic oxygen saturation (Pulse Oximeter Result, SpO_2)

a. Result (%)

b. Time Obtained

C5. Venous oxygen saturation (PO_2 venous, SvO_2)

a. Result (%)

b. Time Obtained

C6. Glascow Coma Score

a1. Eye Opening Result

- 4 = Spontaneous eye opening
- 3 = Eye opening to verbal stimuli
- 2 = Eye opening to pain
- 1 = No Response

a2. Best Verbal Response

- 5 = Subject is oriented and converses
- 4 = Subject is disoriented and converses
- 3 = Subject uses inappropriate words
- 2 = Subject makes incomprehensible sounds
- 1 = No response

a3. Best Motor Response

- 6 = Subject obeys command
- 5 = Subject localizes pain
- 4 = Subject has flexion withdrawal
- 3 = Subject has abnormal flexion (decorticate rigidity)
- 2 = Subject has extension (decerebrate rigidity)
- 1 = No response

a4. Total Score

b. Time Obtained

C7. Is the subject currently receiving oxygen? ○ Yes ○ No (C8a)

a. Oxygen device
- ○ Nasal cannula
- ○ Mask
- ○ Intubated

b. Liters of oxygen received

c. FiO2 (%)

d. Time Obtained

C8. PO_2 Arterial (PaO_2, Oxygen level)

a. Result (mmHg)

b. Time Obtained

C9. Does the subject have a central venous catheter in place? ○ Yes ○ No

C10. Central Venous Pressure (CVP)

a. Result (mmHg)

b. Time Obtained

C11. Does the subject have a pulmonary artery/Swan-Ganz catheter in place? ○ Yes ○ No (C21or C22)

C12. Systemic Vascular Resistance (SVR)

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)

b. Time Obtained

Components of oxygen consumption calculation: Must be done within 30 minutes of one another.

C17. Arterial oxygen saturation (SaO_2)

a. Result (%)

b. Time Obtained

C18. Venous oxygen saturation (SvO_2)

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? ○ Yes ○ No (C23)

C22. Whole blood lactic acid

a. Result (mmol/L)

b. Time Drawn

c. Source of blood
- ○ Arterial
- ○ Peripheral
- ○ Free Flowing Venous Catheter

C23. Was the subject on an intra-aortic balloon pump on this day of assessment?
- ○ Yes
- ○ No

SECTION D: MEDICATION CHECKLIST

D1. Please indicate if the subject received any of the following medications on the date of assessment. ○ Yes ○ No (END)

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

DONE

Transfusion Medicine/Hemostasis Clinical Trials Network

TMH – 08: RECESS Study Day #: _____

Form RE09 – Post-Op Measurements Worksheet

A1. Subject ID: __ __--__ __ __ __ -- __ __ __ -- __ A2. Date of assessment: __ __ / __ __ / __ __ __ __ *(mm/dd/yyyy)*

Section B: LABORATORY DATA

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.

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 ($x10^9$ L)	_____	___ ___:___ ___	B7. ALT (SGPT) (U/L)	_____	___ ___:___ ___
B4. Hemoglobin (g/L)	_____	___ ___:___ ___	B8. Troponin-I (ng/ml)	_____	___ ___:___ ___

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:

C1. Did the subject have any of the following lines in place or arterial puncture on the assessment day? ☐1 Yes ☐2 No **(C2)**

C1a. Pulmonary Artery line/Swan-Ganz catheter ☐1 Yes ☐2 No C1c. Central venous catheter ☐1 Yes ☐2 No C1e. Arterial puncture ☐1 Yes ☐2 No

C1b. Arterial line ☐1 Yes ☐2 No C1d. PICC line ☐1 Yes ☐2 No

C2. Did the subject receive supplemental oxygen on the assessment day? ☐1 Yes ☐2 No **(C3)**

C2a. Oxygen device ☐1 Nasal cannula ☐2 Mask ☐3 Intubated

C2b. Liters of oxygen received: _____

C3. Was the subject on an intra-aortic balloon pump on this day of assessment? ☐1 Yes ☐2 No

Other MODS Measurements:		**a. Result**	**b. Time Obtained**
C4. Heart Rate (beats per minute)	☐-1 Not done	_____	___ ___:___ ___
C5. Blood Pressure (mmHg)	☐-1 Not done	_____ / _____	___ ___:___ ___
C6. PO_2 Arterial (PaO2, Oxygen level) (mmHg)	☐-1 Not done	_____	___ ___:___ ___
C7. FiO_2 (%)	☐-1 Not done	_____	___ ___:___ ___
C8. Mean Arterial Pressure (mmHg)	☐-1 Not done	_____	___ ___:___ ___
C9. Central Venous Pressure (CVP) (mmHg)	☐-1 Not done	_____	___ ___:___ ___

__ __ - __ __ __ __ - __ __ __ - __

Other MODS Measurements continued:

C10. Glasgow Coma Score ☐ -1 Not done

a1. Eye opening result ☐ 4 = Spontaneous eye opening ☐ 3 = Eye opening to verbal stimuli ☐ 2 = Eye opening to pain ☐ 1 = No response

a2. Best verbal response ☐ 5 = Subject is oriented and converses ☐ 4 = Subject is disoriented and converses ☐ 3 = Subject uses inappropriate words ☐ 2 = Subject makes incomprehensible sounds ☐ 1 = No response

a3. Best motor response ☐ 6 = Subject obeys command ☐ 5 = Subject localizes pain ☐ 4 = Subject has flexion withdrawal ☐ 3 = Subject has abnormal flexion (decorticate rigidity) ☐ 2 = Subject has extension (decerebrate rigidity) ☐ 1 = No Response

a4. Total Glasgow Coma Score: _____ **b. Time Obtained** ___ ___:___ ___

Additional Measurements:		**a. Result**	**b. Time Obtained**
C11. Whole Blood Lactic Acid (mmol/L)	☐ -1 Not done	_____	___ ___:___ ___
c. Source of Blood	☐ 1 Arterial ☐ 2 Peripheral ☐ 3 Free Flowing Venous Catheter or PICC line		
C12. Arterial Oxygen Saturation (SaO_2) (%)	☐ -1 Not done	_____	___ ___:___ ___
C13. Systemic Oxygen Saturation (Pulse Oximeter Result, SpO_2) (%)	☐ -1 Not done	_____	___ ___:___ ___
C14. Venous Oxygen Saturation (PO_2 venous, SvO_2) (%)	☐ -1 Not done	_____	___ ___:___ ___
C15. Systemic Vascular Resistance (SVR) (dynes)	☐ -1 Not done	_____	___ ___:___ ___
C16. Pulmonary Capillary Wedge Pressure (PCWP) (mmHg)	☐ -1 Not done	_____	___ ___:___ ___
C17. Cardiac Output (L/min)	☐ -1 Not done	_____	___ ___:___ ___
C18. Cardiac Index (L/min/m^2)	☐ -1 Not done	_____	___ ___:___ ___
C19. Oxygen Consumption as reported on machine/readout (L/min)	☐ -1 Not done	_____	___ ___:___ ___

Components of oxygen consumption calculation (Report if no readout available (C19) and done within 30 minutes of each other.)

C20. Does subject have the 3 components of the oxygen consumption calculation obtained within 30 minutes of each other on the day of assessment? ☐ 1 Yes ☐ 2 No **(D1)**

Parameter		**a. Result**	**b. Time Obtained**
C21. Arterial Oxygen Saturation (SaO2) (%)	☐ -1 Not done	_____	___ ___:___ ___
C22. Venous oxygen saturation (SvO_2) (%)	☐ -1 Not done	_____	___ ___:___ ___
C23. Cardiac Output (L/min)	☐ -1 Not done	_____	___ ___:___ ___

__ __ - __ __ __ __ - __ __ __ - __

Section D: MEDICATION CHECKLIST

D1. Did the subject receive any of the following medications on the date of assessment? ☐1 Yes ☐2 No **(END)**

a. Abiciximab (ReoPro)	☐1 Yes	☐2 No	p. Therapeutic Heparin (low molecular)	☐1 Yes	☐2 No
b. Aprotinin (Trasylol)	☐1 Yes	☐2 No	q. Hirudin	☐1 Yes	☐2 No
c. Argatroban	☐1 Yes	☐2 No	r. Lepirudin	☐1 Yes	☐2 No
d. Aspirin	☐1 Yes	☐2 No	s. Melagatran	☐1 Yes	☐2 No
e. Bivalirudin (Angiomax)	☐1 Yes	☐2 No	t. Nitric Oxide Gas	☐1 Yes	☐2 No
f. Cilostazol (Pletal)	☐1 Yes	☐2 No	u. Prasugrel (Effient)	☐1 Yes	☐2 No
g. Clopidogrel (Plavix)	☐1 Yes	☐2 No	v. Prothrombin Complex Concentrates	☐1 Yes	☐2 No
h. Dabigatran	☐1 Yes	☐2 No	w. Sildenafil (Viagra)	☐1 Yes	☐2 No
i. Desirudin	☐1 Yes	☐2 No	x. Steroids	☐1 Yes	☐2 No
j. Desmopressin (DDAVP, Stimate, Minirin)	☐1 Yes	☐2 No	y. Ticlopidine (Ticlid)	☐1 Yes	☐2 No
k. Direct Thrombin Inhibitors	☐1 Yes	☐2 No	z. Tirofiban (Aggrestat)	☐1 Yes	☐2 No
l. Epsilon Aminocaproic Acid (Amicar)	☐1 Yes	☐2 No	aa. Tranexamic Acid (Cyklokapron)	☐1 Yes	☐2 No
m. Eptifibatide (Integrilin)	☐1 Yes	☐2 No	bb. Warfarin (Coumadin)	☐1 Yes	☐2 No
n. Factor VIIa (NovoSeven)	☐1 Yes	☐2 No	zz. Other anticoagulant or antiplatelet	☐1 Yes	☐2 No
o. Therapeutic Heparin (unfractionated)	☐1 Yes	☐2 No	Specify other:_____		

Transfusion Medicine/Hemostasis Clinical Trials Network

TMH – 08: RECESS Study Day #: _____

Form RE09 – Post-Op Measurements Worksheet

A1. Subject ID: __ __--__ __ __ __ -- __ __ __ -- __ A2. Date of assessment: __ __ / __ __ / __ __ __ __ *(mm/dd/yyyy)*

Section B: LABORATORY DATA

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.

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 (x10^9 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*	

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:

C1. Did the subject have any of the following lines in place or arterial puncture on the assessment day? ☐$_1$ Yes ☐$_2$ No **(C2)**

C1a. Pulmonary Artery line/Swan-Ganz catheter ☐$_1$ Yes ☐$_2$ No

C1b. Arterial line ☐$_1$ Yes ☐$_2$ No

C1c. Central venous catheter ☐$_1$ Yes ☐$_2$ No

C1d. PICC line ☐$_1$ Yes ☐$_2$ No

C1e. Arterial puncture ☐$_1$ Yes ☐$_2$ No

C2. Did the subject receive supplemental oxygen on the assessment day? ☐$_1$ Yes ☐$_2$ No **(C3)**

C2a. Oxygen device ☐$_1$ Nasal cannula ☐$_2$ Mask ☐$_3$ Intubated

C2b. Liters of oxygen received: _____

C3. Was the subject on an intra-aortic balloon pump on this day of assessment? ☐$_1$ Yes ☐$_2$ No

Other MODS Measurements:		**a. Result**	**b. Time Obtained**
C4. Heart Rate (beats per minute)	☐$_{-1}$ Not done	_____	___ ___:___ ___
C5. Blood Pressure (mmHg)	☐$_{-1}$ Not done	_____ / _____	___ ___:___ ___
C6. PO_2 Arterial (PaO2, Oxygen level) (mmHg)	☐$_{-1}$ Not done	_____	___ ___:___ ___
C7. FiO_2 (%)	☐$_{-1}$ Not done	_____	___ ___:___ ___
C8. Mean Arterial Pressure (mmHg)	☐$_{-1}$ Not done	_____	___ ___:___ ___
C9. Central Venous Pressure (CVP) (mmHg)	☐$_{-1}$ Not done	_____	___ ___:___ ___

__ __ - __ __ __ __ - __ __ __ - __

Other MODS Measurements continued:

C10. Glasgow Coma Score ☐ -1 Not done

a1. Eye opening result ☐ 4 = Spontaneous eye opening ☐ 3 = Eye opening to verbal stimuli ☐ 2 = Eye opening to pain ☐ 1 = No response

a2. Best verbal response ☐ 5 = Subject is oriented and converses ☐ 4 = Subject is disoriented and converses ☐ 3 = Subject uses inappropriate words ☐ 2 = Subject makes incomprehensible sounds ☐ 1 = No response

a3. Best motor response ☐ 6 = Subject obeys command ☐ 5 = Subject localizes pain ☐ 4 = Subject has flexion withdrawal ☐ 3 = Subject has abnormal flexion (decorticate rigidity) ☐ 2 = Subject has extension (decerebrate rigidity) ☐ 1 = No Response

a4. Total Glasgow Coma Score: _____ **b. Time Obtained** ___ ___:___ ___

Additional Measurements:		**a. Result**	**b. Time Obtained**
C11. Whole Blood Lactic Acid (mmol/L)	☐ -1 Not done	_____	___ ___:___ ___
c. Source of Blood	☐ 1 Arterial ☐ 2 Peripheral ☐ 3 Free Flowing Venous Catheter or PICC line		
C12. Arterial Oxygen Saturation (SaO_2) (%)	☐ -1 Not done	_____	___ ___:___ ___
C13. Systemic Oxygen Saturation (Pulse Oximeter Result, SpO_2) (%)	☐ -1 Not done	_____	___ ___:___ ___
C14. Venous Oxygen Saturation (PO_2 venous, SvO_2) (%)	☐ -1 Not done	_____	___ ___:___ ___
C15. Systemic Vascular Resistance (SVR) (dynes)	☐ -1 Not done	_____	___ ___:___ ___
C16. Pulmonary Capillary Wedge Pressure (PCWP) (mmHg)	☐ -1 Not done	_____	___ ___:___ ___
C17. Cardiac Output (L/min)	☐ -1 Not done	_____	___ ___:___ ___
C18. Cardiac Index (L/min/m^2)	☐ -1 Not done	_____	___ ___:___ ___
C19. Oxygen Consumption as reported on machine/readout (L/min)	☐ -1 Not done	_____	___ ___:___ ___

Components of oxygen consumption calculation (Report if no readout available (C19) and done within 30 minutes of each other.)

C20. Does subject have the 3 components of the oxygen consumption calculation obtained within 30 minutes of each other on the day of assessment? ☐ 1 Yes ☐ 2 No **(D1)**

Parameter		**a. Result**	**b. Time Obtained**
C21. Arterial Oxygen Saturation (SaO2) (%)	☐ -1 Not done	_____	___ ___:___ ___
C22. Venous oxygen saturation (SvO_2) (%)	☐ -1 Not done	_____	___ ___:___ ___
C23. Cardiac Output (L/min)	☐ -1 Not done	_____	___ ___:___ ___

__ __ - __ __ __ __ - __ __ __ - __

Section D: MEDICATION CHECKLIST

D1. Did the subject receive any of the following medications on the date of assessment? ☐1 Yes ☐2 No **(END)**

a. Abiciximab (ReoPro)	☐1 Yes	☐2 No	p. Therapeutic Heparin (low molecular)	☐1 Yes	☐2 No
b. Aprotinin (Trasylol)	☐1 Yes	☐2 No	q. Hirudin	☐1 Yes	☐2 No
c. Argatroban	☐1 Yes	☐2 No	r. Lepirudin	☐1 Yes	☐2 No
d. Aspirin	☐1 Yes	☐2 No	s. Melagatran	☐1 Yes	☐2 No
e. Bivalirudin (Angiomax)	☐1 Yes	☐2 No	t. Nitric Oxide Gas	☐1 Yes	☐2 No
f. Cilostazol (Pletal)	☐1 Yes	☐2 No	u. Prasugrel (Effient)	☐1 Yes	☐2 No
g. Clopidogrel (Plavix)	☐1 Yes	☐2 No	v. Prothrombin Complex Concentrates	☐1 Yes	☐2 No
h. Dabigatran	☐1 Yes	☐2 No	w. Sildenafil (Viagra)	☐1 Yes	☐2 No
i. Desirudin	☐1 Yes	☐2 No	x. Steroids	☐1 Yes	☐2 No
j. Desmopressin (DDAVP, Stimate, Minirin)	☐1 Yes	☐2 No	y. Ticlopidine (Ticlid)	☐1 Yes	☐2 No
k. Direct Thrombin Inhibitors	☐1 Yes	☐2 No	z. Tirofiban (Aggrestat)	☐1 Yes	☐2 No
l. Epsilon Aminocaproic Acid (Amicar)	☐1 Yes	☐2 No	aa. Tranexamic Acid (Cyklokapron)	☐1 Yes	☐2 No
m. Eptifibatide (Integrilin)	☐1 Yes	☐2 No	bb. Warfarin (Coumadin)	☐1 Yes	☐2 No
n. Factor VIIa (NovoSeven)	☐1 Yes	☐2 No	zz. Other anticoagulant or antiplatelet	☐1 Yes	☐2 No
o. Therapeutic Heparin (unfractionated)	☐1 Yes	☐2 No	Specify other: _____		

Transfusion Medicine/Hemostasis Clinical Trials Network

RE09: Post-Op/Daily Measurement Form
Version: F

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.

	Lab	Result	Time Drawn
B1.	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:

C1. Did the subject have any of the following lines in place or an arterial puncture on the assessment date? ○ Yes ○ No (C2)

a. Pulmonary Artery line/Swan-Ganz catheter ○ Yes ○ No

b. Arterial line ○ Yes ○ No

c. Central venous catheter ○ Yes ○ No

d. PICC line ○ Yes ○ No

e. Arterial Puncture ○ Yes ○ No

C2. Did the subject receive supplemental oxygen at 7:00am? ○ Yes ○ No (C3)

a. Oxygen device
○ Nasal cannula
○ Mask
○ Intubated

b. Liters of oxygen received

C3. Was the subject on an intra-aortic balloon pump on this day? ○ Yes ○ No

Other MODS Measurements:

C4. Heart Rate

a. Result (beats per minute)

b. Time Obtained

C5. Blood Pressure

a. Systolic Blood Pressure (mmHg)

b. Diastolic Blood Pressure (mmHg)

c. Time Obtained

C6. PO_2 Arterial (PaO_2, Oxygen level)

a. Result (mmHg)

b. Time Obtained

C7. FiO_2

a. Result (%)

b. Time Obtained

C8. Mean Arterial Pressure

Temporary Save
Save Reload

a. Result (mmHg)

b. Time Obtained

C9. Central Venous Pressure (CVP)

a. Result (mmHg)

b. Time Obtained

C10. Glasgow Coma Score

a1. Eye Opening Result

- Spontaneous eye opening
- Eye opening to verbal stimuli
- Eye opening to pain
- No Response

a2. Best Verbal Response

- Subject is oriented and converses
- Subject is disoriented and converses
- Subject uses inappropriate words
- Subject makes incomprehensible sounds
- No response

a3. Best Motor Response

- Subject obeys command
- Subject localizes pain
- Subject has flexion withdrawal
- Subject has abnormal flexion (decorticate rigidity)
- Subject has extension (decerebrate rigidity)
- No response

a4. Total Score * *See note below*

b. Time Obtained

* All subjects that are sedated during the performing of the GCS measurement should still have the observed scores reported for the individual components of the GCS based on the actual assessment of the subject, but the overall score must be given one of the specific special codes below rather than the sum of the individual component scores.

- Code 88 = Sedated, Expected to Be Normal: had normal neurologic function for age by history before surgery and no catastrophic events to change that status are clinically evident, but currently unable to assess because of sedation.
- Code 99 = Sedated, Not Normal: neurologic function not normal by pre-operative history (prior stroke, tumor or trauma sequelae, cognitively challenged, behavioral disorder, etc.) or intra-operative history, but currently unable to assess because of sedation.

Additional Measurements:

C11. Whole Blood Lactic Acid

a. Result (mmol/L)

b. Time Drawn

c. Source of blood

- Arterial
- Peripheral
- Free Flowing Venous Catheter or PICC line

C12. Arterial Oxygen Saturation (SaO_2)

a. Result (%)

b. Time Obtained

C13. Systemic Oxygen Saturation (Pulse Oximeter Result, SpO_2)

a. Result (%)

b. Time Obtained

SECTION D: MEDICATION CHECKLIST

D1. Please indicate if the subject received any of the following medications on the date of assessment. Yes / No (END)

		Yes	No	
a.	Abiciximab (ReoPro)			
b.	Aprotinin (Trasylol)			
c.	Argatroban			
d.	Aspirin			
e.	Bivalirudin (Angiomax)			
f.	Cilostazol(Pletal)			
g.	Clopidogrel (Plavix)			
h.	Dabigatran			
i.	Desirudin			
j.	Desmopressin (DDAVP, Stimate, Minirin)			
k.	Direct Thrombin Inhibitors			

l.	Factor VIIa (NovoSeven)	○	○	
m.	Epsilon Aminocaproic Acid (Amicar)	○	○	
n.	Eptifibatide (Integrilin)	○	○	
o.	Therapeutic heparin (unfractionated)	○	○	
p.	Therapuetic heparin (low molecular)	○	○	
q.	Hirudin	○	○	
r.	Lepirudin	○	○	
s.	Melagatran	○	○	
t.	Nitric Oxide Gas	○	○	
u.	Prasugrel (Effient)	○	○	
v.	Prothrombin Complex Concentrates	○	○	
w.	Sildenafil (Viagra)	○	○	
x.	Steroids	○	○	
y.	Ticlopidine (Ticlid)	○	○	
z.	Tirofiban (Aggrestat)	○	○	
aa.	Tranexamic Acid (Cyklokapron)	○	○	
bb.	Warfarin (Coumadin)	○	○	
zz.	Other anticoagulant or antiplatelet	○	○	
	Specify other			

DONE

Transfusion Medicine/Hemostasis Clinical Trials Network

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
- Apheresis
- Whole blood collection

B3. ABO group of unit
- A
- B
- AB
- O

B4. Rh type
- Positive
- Negative

B5. Collection Date

B6. Storage medium
- AS1
- AS3
- AS5
- CPDA1 (Protocol Deviation)
- Other (Protocol Deviation)

a. Specify other

B7. Was the unit irradiated?
- Yes
- No (B8)

a. Date of irradiation

b. Time of irradiation

B8. Was the unit leukoreduced?
- Yes
- No (Protocol Deviation)

B9. Was the unit washed?
- Yes (Protocol Deviation)
- No (B10)

a. Date unit washed

b. Time unit washed

B10. Was this a non-study unit for one of the reasons listed below?
- Yes (Protocol Deviation)
- No (END)

Check all that apply:

a. Autologous

b. Directed donation

c. Deglycerolized ☐

d. Frozen ☐

DONE

Transfusion Medicine/Hemostasis Clinical Trials Network

RE10: RBC Product Form
Version: B

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
- Apheresis
- Whole blood collection

B3. ABO group of unit
- A
- B
- AB
- O

B4. Rh type
- Positive
- Negative

B5. Collection Date

B6. Storage medium
- AS1
- AS3
- AS5
- CPDA1 (Protocol Deviation)
- Other (Protocol Deviation)

a. Specify other

B7. Was the unit irradiated?
- Yes
- No (B8)

a. Date of irradiation

b. Time of irradiation

B8. Was the unit leukoreduced?
- Yes
- No (Protocol Deviation)

B9. Was the unit washed?
- Yes (Protocol Deviation)
- No (B10)

a. Date unit washed

b. Time unit washed

B10. Was the unit volume reduced?
- Yes (Protocol Deviation)
- No

B11. Was this a non-study unit for one of the reasons listed below?
- Yes (Protocol Deviation)
- No (END)

Check all that apply:

a. Autologous

b. Directed donation ☐

c. Deglycerolized ☐

d. Frozen ☐

DONE

Transfusion Medicine/Hemostasis Clinical Trials Network

TMH – 08: RECESS

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? ☐1 Yes ☐2 No

B3. Transfusion start date __ __ / __ __ / __ __ __ __ *(mm/dd/yyyy)*

B3a. Transfusion start time ___ ___:___ ___ *(24 hour clock)*

B4. Was the entire unit transfused? ☐1 Yes **(B5)** ☐2 No

B4a. Estimated volume transfused (mL) _____

B5. Was the unit washed after it was released from the Blood Bank?

☐1 Yes *(Protocol Deviation)* ☐2 No **(END)** ☐3 Unknown **(END)**

B5a. Date unit washed __ __ / __ __ / __ __ __ __ *(mm/dd/yyyy)*

B5b. Time unit washed ___ ___:___ ___ *(24 hour clock)*

Transfusion Medicine/Hemostasis Clinical Trials Network

RE12: Transfusion of Other Blood Products Form
Version: A

SECTION A: GENERAL INFORMATION

A1. Subject ID

SECTION B: BLOOD PRODUCT ADMINISTRATION

B1. Type of product transfused
- Apheresis Platelets(B4a)
- Whole Blood Derived Platelets(B4b)
- Plasma(B4c)
- Cryoprecipitate(B4b)

a. Was the unit(s) leukoreduced?
- Yes
- 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?
- Yes (END)
- No

a. Estimated percent of unit volume transfused (mL)

DONE

Transfusion Medicine/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

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

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 INFORMATION

B1. Interview disposition code

B2. Mode of contact

- Telephone
- Face-to-face

B3. Number of calls

B4. Date of contact

B5. Interviewer initials

B6. Comment

DONE

Transfusion Medicine/Hemostasis Clinical Trials Network

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 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):

- Daily Troponin-I result obtained closest to 7:00 am on Day 0 through Day 7, hospital discharge or death, whichever comes first .
- If hospitalized after day 7, Troponin-I result obtained closest to 7:00 am on Day 28 or discharge, whichever comes first.

Additional Results (may be ordered, if any were done):

- Additional Troponin-I results obtained Day 0 – Day 7 that are 5 times the upper limit of normal or higher.
- Daily Troponin-I results obtained closest to 7:00 am on Days 8-27 done as part of standard of care.

B1. a. Troponin I result (ng/mL)

B1. b. Date Drawn

B1. c. Time Drawn

DONE

Transfusion Medicine/Hemostasis Clinical Trials Network

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
- Less 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):

- Pre-op Troponin-I result obtained closest to the start time of surgery and within 30 days prior to surgery.
- Daily Troponin-I result obtained closest to 7:00 am on Day 0 through Day 7, hospital discharge or death, whichever comes first.
- If hospitalized after day 7, Troponin-I result obtained closest to 7:00 am on Day 28 or discharge, whichever comes first.

Additional Results (may be ordered, if any were done):

- Additional Troponin-I results obtained Day 0 – Day 7 that are 5 times the upper limit of normal or higher.
- Daily Troponin-I results obtained closest to 7:00 am on Days 8-27 done as part of standard of care.

B1. a. Troponin I result (ng/mL)
- Less than (<)
- Equal to (=)
- Greater than (>)

B1. b. Date Drawn

B1. c. Time Drawn

DONE

Transfusion Medicine/Hemostasis Clinical Trials Network

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? Yes 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? Yes No

a. Date readmitted to ICU

b. Time readmitted to ICU

B6. Initial date extubated

a. Initial time extubated

B7. Was the subject reintubated? Yes 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	○ Yes ○ No
C9. Phenylephrine	○ Yes ○ No

DONE

Transfusion Medicine/Hemostasis Clinical Trials Network

RE26: End of Study Form
Version: A

SECTION A: GENERAL INFORMATION

A1. Subject ID

SECTION B: END OF STUDY INFORMATION

B1. What was the primary reason for the end of study?

- Completion of 28 day follow-up (Subject alive at Day 28)
- Subject (or guardian) decision to withdraw
- Death
- Physician decision to withdraw subject
- Study terminated at site
- Entire study terminated
- Subject did not receive a RBC transfusion intra-operatively or within the first 96 hours after surgery
- Lost to follow-up
- No surgery for 30 days
- Other

a. Specify other

B2. End of Study/Date of Death

B3. Comments

DONE

Transfusion Medicine/Hemostasis Clinical Trials Network

TMH – 08: RECESS

Form RE26 – End of Study Worksheet

Section A: GENERAL INFORMATION

A1. Subject ID: __ __--__ __ __ __ -- __ __ __ -- __

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)
- ☐2 Subject (or guardian) decision to withdraw
- ☐3 Death
- ☐4 Physician decision to withdraw subject
- ☐5 Study terminated at site
- ☐6 Entire study terminated
- ☐7 Subject did not receive an RBC transfusion between randomization and 96 hours after the end of surgery
- ☐8 Lost to follow-up
- ☐9 No surgery for 30 days
- ☐10 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: _____

_____

Transfusion Medicine/Hemostasis Clinical Trials Network

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 (MedDRA category)

B2. a. Date of Onset

b. Time of Onset

B3. Assessment Date

B4. Intensity

- Mild
- Moderate
- Severe

B5. Relationship to RBC transfusion

- Not related
- 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? 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 questions.

	Yes	No
a. None (Observation)		
b. Procedure (If yes, discuss procedure in narrative)		
c. Medication (If yes, discuss medication in narrative)		

d. Other (If yes, discuss other in narrative) ○ ○

d1. Specify other

B9. Outcome

- ○ Resolved without sequelae
- ○ Resolved with sequelae
- ○ Not resolved (B10)
- ○ Not resolved at death (B10)

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	○	○
b. Requires hospitalization or prolongation of existing hospitalization	○	○
c. Results in a persistent or significant disability/incapacitation	○	○
d. Medically important event	○	○
e. Results in a congenital anomaly/birth defect	○	○
f. Results in death	○	○

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.

DONE

Transfusion Medicine/Hemostasis Clinical Trials Network

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

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:

- 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
- Probably related
- 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? 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 questions.

	Yes	No
a. None (Observation)		
b. Procedure (If yes, discuss procedure in narrative)		

c. Medication (If yes, discuss medication in narrative) ○ ○

d. Other (If yes, discuss other in narrative) ○ ○

d1. Specify other

B9. Outcome

- ○ Resolved without sequelae
- ○ Resolved with sequelae
- ○ Not resolved (B10)
- ○ Not resolved at death (B10)

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	○	○
b. Requires hospitalization or prolongation of existing hospitalization	○	○
c. Results in a persistent or significant disability/incapacitation	○	○
d. Medically important event	○	○
e. Results in a congenital anomaly/birth defect	○	○
f. Results in death	○	○

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.

DONE

Transfusion Medicine/Hemostasis Clinical Trials Network

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

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/Report Date

B4. Intensity/Grade of this event:

- 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
- Probably related
- 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? 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 questions.

Yes No

a. None (Observation)

b. Procedure (If yes, discuss procedure in narrative)

c. Medication (If yes, discuss medication in narrative)

d. Other (If yes, discuss other in narrative)

d1. Specify other

B9. Outcome

- Resolved without sequelae
- Resolved with sequelae
- Not resolved (B10)
- Not resolved at death (B10)

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		
b. Requires hospitalization or prolongation of existing hospitalization		
c. Results in a persistent or significant disability/incapacitation		
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).*		
e. Results in a congenital anomaly/birth defect		
f. Results in death		

f1. Date of death

B11. 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		
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.		

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

Transfusion Medicine/Hemostasis Clinical Trials Network

RE81: Infection/Sepsis Event Form
Version: A

SECTION A: GENERAL INFORMATION

A1. Subject ID

SECTION B: ADVERSE EVENT INFORMATION

B1. Adverse Event (record diagnosis)

a. Adverse Event (MedDRA category)

B2a. Date of Onset

B2b. Time of Onset

B3. Assessment Date

B4. Intensity
- Mild
- Moderate
- Severe

B5. Relationship to RBC transfusion
- Not related
- Possibly related
- Probably related
- Related

B6. Did the subject have a localized infection? Yes / No (B7)

a. Infection Category
- Abdominal/Pelvic
- Gastrointestinal
- IV Catheter
- Mediastinum
- Pneumonia
- Urinary Tract
- Other localized infection

a1. Specify other

B7. Did the subject have sepsis (i.e., a blood or systemic infection)? Yes / No (B8a)

a. Was a positive culture from blood and/or CSF obtained? Yes / No (B8a)

b. Date of culture

c. Site(s) of culture
- Blood
- Cerebrospinal fluid

Blood and Cerebrospinal fluid

d. Organism(s)

B8. Did the subject have any of the following +/- 24 hours of the diagnosis of sepsis?

	Yes	No
a. Temperature < 36 degrees Celsius or > 38 degrees Celsius?		
b. Heart rate > 90 bpm?		
c. Respiration rate > 20 breaths/min or PaCO2 < 32mmHg?		
d. White blood cell count > 12,000 or < 4000 cell/mm3 or > 10% bands?		

B9. What was the treatment for this event? Answer all questions.

	Yes	No
a. None (observation)		
b. Procedure (If yes, discuss procedure in narrative)		
c. Medication (If yes, discuss medication in narrative)		
d. Other (If yes, discuss other in narrative)		

d1. Specify other

B10. Outcome

- Resolved without sequelae
- Resolved with sequelae
- Not resolved (B11a)
- Not resolved at death (B11a)

a. Date event resolved

B11. What, if any, of the following serious criteria were met with this event? Answer all questions.

	Yes	No
a. Life-threatening		
b. Requires hospitalization or prolongation of existing hospitalization		
c. Permanent disability/incapacitation		
d. Medically important event		
e. Results in a congenital anomaly/birth defect		
f. Results in death		

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

Transfusion Medicine/Hemostasis Clinical Trials Network

RE81: Infection/Sepsis Event Form
Version: B

SECTION A: GENERAL INFORMATION

A1. Subject ID

SECTION B: ADVERSE EVENT INFORMATION

B1. Adverse Event (record diagnosis)

a. Adverse Event (MedDRA category)

(If not found enter -6)

B2a. Date of Onset

B2b. Time of Onset

B3. Assessment Date

B4. Intensity/Grade of this event:

- 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
- Probably related
- Related

B6. Did the subject have a localized infection?

- Yes
- No (B7)

a. Infection Category

- Abdominal/Pelvic
- Gastrointestinal
- IV Catheter
- Mediastinum
- Pneumonia
- Urinary Tract
- Other localized infection

a1. Specify other

B7. Did the subject have sepsis (i.e., a blood or systemic infection)?

- Yes
- No (B8a)

a. Was a positive culture from blood and/or CSF obtained?

- Yes
- No (B8a)

b. Date of culture

c. Site(s) of culture
- ○ Blood
- ○ Cerebrospinal fluid
- ○ Blood and Cerebrospinal fluid

d. Organism(s)

B8. Did the subject have any of the following +/- 24 hours of the diagnosis of sepsis?

	Yes	No
a. Temperature < 36 degrees Celsius or > 38 degrees Celsius?	○	○
b. Heart rate > 90 bpm?	○	○
c. Respiration rate > 20 breaths/min or PaCO2 < 32mmHg?	○	○
d. White blood cell count > 12,000 or < 4000 cell/mm3 or > 10% bands?	○	○

B9. What was the treatment for this event? Answer all questions.

	Yes	No
a. None (observation)	○	○
b. Procedure (If yes, discuss procedure in narrative)	○	○
c. Medication (If yes, discuss medication in narrative)	○	○
d. Other (If yes, discuss other in narrative)	○	○

d1. Specify other

B10. Outcome
- ○ Resolved without sequelae
- ○ Resolved with sequelae
- ○ Not resolved (B11a)
- ○ Not resolved at death (B11a)

a. Date event resolved

B11. What, if any, of the following serious criteria were met with this event? Answer all questions.

	Yes	No
a. Life-threatening	○	○
b. Requires hospitalization or prolongation of existing hospitalization	○	○
c. Permanent disability/incapacitation	○	○
d. Medically important event	○	○

e. Results in a congenital anomaly/birth defect ○ ○

f. Results in death ○ ○

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

Transfusion Medicine/Hemostasis Clinical Trials Network

RE81: Infection/Sepsis Event Form
Version: C

SECTION A: GENERAL INFORMATION

A1. Subject ID

SECTION B: ADVERSE EVENT INFORMATION

B1. Adverse Event (record diagnosis)

a. Adverse Event (MedDRA category)

(If not found enter -6)

B2a. Date of Onset

B2b. Time of Onset

B3. Assessment/Report Date

B4. Intensity/Grade of this event:

- 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
- Probably related
- Related

B6. Did the subject have a localized infection? Yes No (B7)

a. Infection Category

- Abdominal/Pelvic
- Gastrointestinal
- IV Catheter
- Mediastinum
- Pneumonia
- Urinary Tract
- Other localized infection

a1. Specify other

B7. Did the subject have sepsis (i.e., a blood or systemic infection)? Yes No (B8a)

a. Was a positive culture from blood Yes No (B8a)

and/or CSF obtained?

b. Date of culture

c. Site(s) of culture
- Blood
- Cerebrospinal fluid
- Blood and Cerebrospinal fluid

d. Organism(s)

B8. Did the subject have any of the following +/- 24 hours of the diagnosis of infection?

	Yes	No
a. Temperature < 36 degrees Celsius or > 38 degrees Celsius?		
b. Heart rate > 90 bpm?		
c. Respiration rate > 20 breaths/min or PaCO2 < 32mmHg?		
d. White blood cell count > 12,000 or < 4000 cell/mm3 or > 10% bands?		

B9. What was the treatment for this event? Answer all questions.

	Yes	No
a. None (observation)		
b. Procedure (If yes, discuss procedure in narrative)		
c. Medication (If yes, discuss medication in narrative)		
d. Other (If yes, discuss other in narrative)		

d1. Specify other

B10. Outcome
- Resolved without sequelae
- Resolved with sequelae
- Not resolved (B11a)
- Not resolved at death (B11a)

a. Date event resolved

B11. What, if any, of the following serious criteria were met with this event? Answer all questions.

	Yes	No
a. Life-threatening		
b. Requires hospitalization or prolongation of existing hospitalization		
c. Permanent disability/incapacitation		

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 (11a-c, e-f).

e. Results in a congenital anomaly/birth defect

f. Results in death

f1. Date of death

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		
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? Yes No

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.

DONE

Transfusion Medicine/Hemostasis Clinical Trials Network

RE82: Renal Failure Event Form
Version: A

SECTION A: GENERAL INFORMATION

A1. Subject ID

SECTION B: ADVERSE EVENT INFORMATION

B1. Adverse Event (record diagnosis)

a. Adverse Event (MedDRA category)

a. Date of Onset

b. Time of Onset

B3. Assessment Date

B4. Intensity
- Mild
- Moderate
- Severe

B5. Relationship to RBC transfusion
- Not related
- Possibly related
- Probably related
- Related

B6. Has the subject experienced any of the following:

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? ○ Yes ○ No (B6d)

1. Date dialysis initiated

d. Hemofiltration? ○ Yes ○ No (B7a)

1. Date hemofiltration initiated

B7. What was the treatment for this event? Answer all questions.

	Yes	No
a. None (Observation)	○	○
b. Procedure (If yes, discuss procedure in narrative)	○	○
c. Medication (If yes, discuss medication in narrative)	○	○
d. Other (If yes, discuss other in narrative)	○	○

1. Specify other

B8. Outcome

○ Resolved without sequalea
○ Resolved with sequelae
○ Not resolved (B9a)
○ Not resolved at death (B9a)

a. Date event resolved

B8. What, if any, the following serious criteria were met with this event? Answer all questions.

	Yes	No
a. Life-threatening	○	○
b. Requires hospitalization or prolongation of existing hospitalization	○	○
c. Results in a persistent or significant disability/incapacitation	○	○
d. Medically important event	○	○
e. Results in a congenital anomaly/birth defect	○	○
f. Results in death	○	○

1. Date of death

B10. Was the subject withdrawn from the study due to this event? ○ Yes ○ 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

Transfusion Medicine/Hemostasis Clinical Trials Network

RE82: Renal Failure Event Form
Version: B

SECTION A: GENERAL INFORMATION

A1. Subject ID

SECTION B: RENAL FAILURE 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::

- 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
- Probably related
- Related

B6. **Has the subject experienced any of the following:**

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? ○ Yes ○ No (B6d)

1. Date dialysis initiated

d. Hemofiltration? ○ Yes ○ No (B7a)

1. Date hemofiltration initiated

B7. **What was the treatment for this event? Answer all questions.**

	Yes	No
a. None (Observation)	○	○
b. Procedure (If yes, discuss procedure in narrative)	○	○
c. Medication (If yes, discuss medication in narrative)	○	○
d. Other (If yes, discuss other in narrative)	○	○

1. Specify other

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	○	○
b. Requires hospitalization or prolongation of existing hospitalization	○	○
c. Results in a persistent or significant disability/incapacitation	○	○
d. Medically important event	○	○
e. Results in a congenital anomaly/birth defect	○	○
f. Results in death	○	○

1. Date of death

B10. Was the subject withdrawn from the study due to this event? ○ Yes ○ 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

Transfusion Medicine/Hemostasis Clinical Trials Network

RE82: Renal Event Form
Version: C

SECTION A: GENERAL INFORMATION

A1. Subject ID

SECTION B: RENAL FAILURE 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/Report Date

B4. Intensity/Grade of this event:

- 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
- Probably related
- Related

B6. Has the subject experienced any of the following:

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? ○ Yes ○ No (B6d)

1. Date dialysis initiated

d. Hemofiltration? ○ Yes ○ No (B7a)

1. Date hemofiltration initiated

B7. What was the treatment for this event? Answer all questions.

	Yes	No
a. None (Observation)	○	○
b. Procedure (If yes, discuss procedure in narrative)	○	○
c. Medication (If yes, discuss medication in narrative)	○	○
d. Other (If yes, discuss other in narrative)	○	○

1. Specify other

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	○	○
b. Requires hospitalization or prolongation of existing hospitalization	○	○
c. Results in a persistent or significant disability/incapacitation	○	○
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 ○ ○

f. Results in death ○ ○

1. Date of death

B10. 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	○	○
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.	○	○

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.

DONE

Transfusion Medicine/Hemostasis Clinical Trials Network

RE83: Other Adverse Event Form
Version: A

SECTION A: GENERAL INFORMATION

A1. Subject ID

SECTION B: ADVERSE EVENT INFORMATION

B1. Adverse Event (record diagnosis)

a. Adverse Event (MedDRA category)

a. Date of Onset

b. Time of Onset

B3. Assessment Date

B4. Intensity

- Mild
- Moderate
- Severe

B5. Relationship to RBC transfusion

- Not related
- Possibly related
- Probably related
- Related

B6. What was the treatment for this event? Answer all questions.

	Yes	No
a. None (Observation)		
b. Procedure (If yes, discuss procedure in narrative)		
c. Medication (If yes, discuss medication in narrative)		
d. Other (If yes, discuss other in narrative)		

1. Specify other

B7. Outcome

- Resolved without sequelae
- Resolved with sequelae
- Not resolved (B7a)
- 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	○	○
b. Requires hospitalization or prolongation of existing hospitalization	○	○
c. Results in a persistent or significant disability/incapacitation	○	○
d. Medically important event	○	○
e. Results in congenital anomaly/birth defect	○	○
f. Results in death	○	○
1. Date of death		

B9. Was the subject withdrawn from the study due to this event? ○ Yes ○ 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.

DONE

Transfusion Medicine/Hemostasis Clinical Trials Network

RE83: Other Adverse Event Form
Version: B

SECTION A: GENERAL INFORMATION

A1. Subject ID

SECTION B: ADVERSE 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:

- 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
- Probably related
- Related

B6. **What was the treatment for this event? Answer all questions.**

	Yes	No
a. None (Observation)		
b. Procedure (If yes, discuss procedure in narrative)		
c. Medication (If yes, discuss medication in narrative)		
d. Other (If yes, discuss other in narrative)		

1. Specify other

B7. Outcome

- Resolved without sequelae
- Resolved with sequelae
- Not resolved (B7a)
- 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	○	○
b. Requires hospitalization or prolongation of existing hospitalization	○	○
c. Results in a persistent or significant disability/incapacitation	○	○
d. Medically important event	○	○
e. Results in congenital anomaly/birth defect	○	○
f. Results in death	○	○

1. Date of death

B9. Was the subject withdrawn from the study due to this event? ○ Yes ○ 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.

DONE

Transfusion Medicine/Hemostasis Clinical Trials Network

RE83: Other Adverse Event Form
Version: C

SECTION A: GENERAL INFORMATION

A1. Subject ID

SECTION B: ADVERSE 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/Report Date

B4. Intensity/Grade of this event:

- 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
- Probably related
- Related

B6. What was the treatment for this event? Answer all questions.

	Yes	No
a. None (Observation)		
b. Procedure (If yes, discuss procedure in narrative)		
c. Medication (If yes, discuss medication in narrative)		
d. Other (If yes, discuss other in narrative)		

1. Specify other

B7. Outcome

- Resolved without sequelae
- Resolved with sequelae
- Not resolved (B8a)

Not resolved at death (B8a)

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		
b. Requires hospitalization or prolongation of existing hospitalization		
c. Results in a persistent or significant disability/incapacitation		
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).*		
e. Results in congenital anomaly/birth defect		
f. Results in death		

1. Date of death

B9. 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		
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.		

B10. Was the subject withdrawn from the study due to this event? Yes 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

Transfusion Medicine/Hemostasis Clinical Trials Network

RE84: Abnormal Lab Adverse Event Form
Version: A

SECTION A: GENERAL INFORMATION

A1. Subject ID

SECTION B: ADVERSE 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/Report Date 09/03/211

B4. Intensity/Grade of this event:
- 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
- Probably related
- Related

B6. Which event are you reporting?
- Hyperkalemia (B7)
- Hyperphosphatemia (B8)
- Hypocalcemia (B9)
- Hyperbilirubinemia (B11)

B7. Hyperkalemia

A. Potassium Value *(mmol/L)*	B. Date Drawn *(mm/dd/yyyy)*	C. Time Drawn *(24 hour clock)*

B8. Hyperphosphatemia

A. Phosphorous Value *(mg/dL)*	B. Date Drawn *(mm/dd/yyyy)*	C. Time Drawn *(24 hour clock)*

B9. Hypocalcemia

* If you do not have calcium values for hypocalcemia data enter "-1" and enter ionized calcium results

A. Calcium Value* *(mg/dL)*	B. Date Drawn *(mm/dd/yyyy)*	C. Time Drawn *(24 hour clock)*

B10. Ionized calcium

**If you do not have ionized calcium levels data enter "-1"

A. Ionized Calcium Value** *(mmol/L)*	B. Date Drawn *(mm/dd/yyyy)*	C. Time Drawn *(24 hour clock)*

B11. Hyperbilirubinemia

A. Date Drawn *(mm/dd/yyyy)*	B. Time Drawn *(24 hour clock)*	C. Total Bilirubin Value *(mg/dL)*	D. Direct Bilirubin Value *(mg/dL)*	E. Indirect Bilirubin Value *(mg/dL)*

B12. Was an LDH done? ○ Yes ○ No (B13)

A. LDH Value *(U/L)*	B. Date Drawn *(mm/dd/yyyy)*	C. Time Drawn *(24 hour clock)*

B13. Was a DAT (Direct Antigloblin Test) done? ○ Yes ○ No (B15)

A. DAT Result	B. Date Drawn *(mm/dd/yyyy)*	C. Time Drawn *(24 hour clock)*	D. Polyspecific	E. IgG	F. C3	G. Eluate
○ Postive ○ Negative			○ Postive ○ Negative ○ Not Done	○ Postive ○ Negative ○ Not Done	○ Postive ○ Negative ○ Not Done	○ Alloantibody Identified ○ No Alloantibody Identified ○ Not Done

B14. Was there a pre-transfusion DAT? ○ Yes ○ No (B15)

A. Result	B. Date Drawn *(mm/dd/yyyy)*	C. Time Drawn *(24 hour clock)*
○ Postive ○ Negative		

B15. Was an ultrasound of the liver and/or gallbaldder performed? ○ Yes ○ No (B16)

a. Identify the organ(s) ○ Liver

- Gallbladder
- Both

b. Detail the findings of the ultrasound

B16. What was the treatment for this event? Answer all questions.

	Yes	No
a. None (Observation)		•
b. Procedure (If yes, discuss procedure in narrative)		
c. Medication (If yes, discuss medication in narrative)		
d. Other (If yes, discuss other in narrative)		

Specify other

B17. Outcome

- Resolved without sequelae
- Resolved with sequelae
- Not resolved (B18)
- Not resolved at death (B18)

a. Date of resolution

B18. What, if any, of the following serious criteria were met with this event? Answer all questions.

	Yes	No
a. Life-threatening		
b. Requires hospitalization or prolongation of existing hospitalization		
c. Results in a persistent or significant disability/incapacitation		
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 (B18a-c, e-f).*		
e. Results in congenital anomaly/birth defect		
f. Results in death		

1. Date of death

B19. Was the subject withdrawn from the study due to this event? Yes / No

B20. 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

Transfusion Medicine/Hemostasis Clinical Trials Network

RE84: Abnormal Lab Adverse Event Form
Version: B

SECTION A: GENERAL INFORMATION

A1. Subject ID

SECTION B: ADVERSE 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/Report Date

B4. Intensity/Grade of this event:

- 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
- Probably related
- Related

B6. Which event are you reporting?

- Hyperkalemia (B7)
- Hyperphosphatemia (B8)
- Hypocalcemia (B9)
- Hyperbilirubinemia (B11)

B7. Hyperkalemia

A. Potassium Value *(mmol/L)*	B. Date Drawn *(mm/dd/yyyy)*	C. Time Drawn *(24 hour clock)*

B8. Hyperphosphatemia

A. Phosphorous Value *(mg/dL)*	B. Date Drawn *(mm/dd/yyyy)*	C. Time Drawn *(24 hour clock)*

B9. Hypocalcemia

* If you do not have calcium values for hypocalcemia data enter "-1" and enter ionized calcium results

A. Calcium Value* *(mg/dL)*	B. Date Drawn *(mm/dd/yyyy)*	C. Time Drawn *(24 hour clock)*

B10. Ionized calcium

**If you do not have ionized calcium levels data enter "-1"

A. Ionized Calcium Value** *(mmol/L)*	B. Date Drawn *(mm/dd/yyyy)*	C. Time Drawn *(24 hour clock)*

B11. Hyperbilirubinemia

A. Date Drawn *(mm/dd/yyyy)*	B. Time Drawn *(24 hour clock)*	C. Total Bilirubin Value *(mg/dL)*	D. Direct Bilirubin Value *(mg/dL)*	E. Indirect Bilirubin Value *(mg/dL)*

B12. Was an LDH done? ○ Yes ○ No (B13)

A. LDH Value *(U/L)*	B. Date Drawn *(mm/dd/yyyy)*	C. Time Drawn *(24 hour clock)*

B13. Was a DAT (Direct Antigloblin Test) done? ○ 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
○ Postive ○ Negative			○ Postive ○ Negative ○ Not Done	○ Postive ○ Negative ○ Not Done	○ Postive ○ Negative ○ Not Done	○ Alloantibody Identified ○ No Alloantibody Identified ○ Not Done

B14. Was there a pre-transfusion DAT? ○ Yes ○ No (B15)

A. Result	B. Date Drawn *(mm/dd/yyyy)*	C. Time Drawn *(24 hour clock)*
○ Postive ○ Negative		

B15. Was an ultrasound of the liver and/or gallbaldder performed? ○ Yes ○ No (B16)

a. Identify the organ(s) ○ Liver

- Gallbladder
- Both

b. Detail the findings of the ultrasound

B16. What was the treatment for this event? Answer all questions.

	Yes	No
a. None (Observation)		
b. Procedure (If yes, discuss procedure in narrative)		
c. Medication (If yes, discuss medication in narrative)		
d. Other (If yes, discuss other in narrative)		

Specify other

B17. Outcome

- Resolved without sequelae
- Resolved with sequelae
- Not resolved (B18)
- Not resolved at death (B18)

a. Date of resolution

B18. What, if any, of the following serious criteria were met with this event? Answer all questions.

	Yes	No
a. Life-threatening		
b. Requires hospitalization or prolongation of existing hospitalization		
c. Results in a persistent or significant disability/incapacitation		
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 (B18a-c, e-f).*		
e. Results in congenital anomaly/birth defect		
f. Results in death		

1. Date of death

B19. 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 ○ ○

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. ○ ○

B20. Was the subject withdrawn from the study due to this event? ○ Yes ○ No

B21. 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

Transfusion Medicine/Hemostasis Clinical Trials Network

RE88: Transfusion Medicine Event Review Form
Version: A

SECTION A: GENERAL INFORMATION

A1. Subject ID

A2. Date of Review

A3. Initials of Reviewer

SECTION B: ADVERSE EVENT INFORMATION

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?

- Mild/Grade 1
- Moderate/Grade 2
- Severe/Grade 3
- Life Threatening/Grade 4
- Death/Grade 5

B4. In your opinion, what is the relationship of the adverse event to the RBC transfusion?

- Not related
- Possibly related
- Probably related
- Related

In your 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).* — Yes / No

B5e.	Results in congenital anomaly/birth defect	○ Yes ◉ No
B5f.	Results in death	○ Yes ◉ No
B6.	Please provide a brief summary of your review of this event:	

DONE

Transfusion Medicine/Hemostasis Clinical Trials Network

RE89: Cardiac Surgery Event Review Form
Version: A

SECTION A: GENERAL INFORMATION

A1. Subject ID

A2. Date of Review

A3. Initials of Reviewer

SECTION B: ADVERSE EVENT INFORMATION

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) 0

B3. In your opinion, what was the intensity/grade of the event?

- Mild/Grade 1
- Moderate/Grade 2
- Severe/Grade 3
- Life Threatening/Grade 4
- Death/Grade 5

B4. In your opinion, what is the relationship of the adverse event to the RBC transfusion?

- Not related
- Possibly related
- Probably related
- Related

In your 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 — Yes / No

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).

B5e.	Results in congenital anomaly/birth defect	○ Yes ◉ No
B5f.	Results in death	◉ Yes ○ No
B6.	Please provide a brief summary of your review of this event:	

DONE

Transfusion Medicine/Hemostasis Clinical Trials Network

RE90: Unblinding Form
Version: A

SECTION A: GENERAL INFORMATION

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? ○ Yes ○ 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 ○ Yes ○ No

c. Physician request ○ Yes ○ No

d. Error ○ Yes ○ No

e. Other Reason: ○ Yes ○ No (B5)

e1. Specify other reason

B5. Provide a brief description of how and/or why disclosure occurred:

B6. Date of disclosure of treatment arm assignment:

DONE

Transfusion Medicine/Hemostasis Clinical Trials Network

RE91: Protocol Deviation/Unusual Event Form
Version: A

SECTION A: GENERAL INFORMATION

A1. Subject ID

A2. Date form completed *(mm/dd/yyyy)*

A3. Initials of person completing form

SECTION B: PROTOCOL DEVIATION/ UNUSUAL EVENT

B1. Is this deviation/event related to an RBC product?

B2. Unit ID of product:

B3. Type 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:

B7a. Code: 1 *(DCC use only)*

B7b. Code: 2 *(DCC use only)*

B7c. Code: 3 *(DCC use only)*

DONE

Transfusion Medicine/Hemostasis Clinical Trials Network

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 1 2 3		16 = Patient/family refused consent (did not want "old" blood)	
2 = TRUST Score not able to be calculated--inadequate 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_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)) pre-operatively		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

Transfusion Medicine/Hemostasis Clinical Trials Network

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 ○ Male ◉ Female

Disposition Codes		Disposition Codes	
1 = TRUST score < 3 Calculated TRUST score ○ 0 ○ 1 ○ 2	☐	16 = Patient/family refused consent (did not want "old" blood)	☐
2 = TRUST Score not able to be calculated--inadequate 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_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)) pre-operatively	☐	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