PROPPR

Pragmatic, **R**andomized **O**ptimal **P**latelet and **P**lasma **R**atios

Case Report Forms

Document Version Date: 12 JUL 2013

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General Instructions:

- Enter all dates in **DD/MMM/YY** format. Enter all times in **HH:MM** using 24hr clock format.
- Print additional form pages if needed. Label additional form pages using a decimal point followed by sequential numbers. (Example: Page 5.01, 5.02)
- Use the following codes in data fields with unknown values:

NA = Not Applicable (e-CRF Code **–995**)	**ND** = Not Detectable (e-CRF Code **–996**)	**NK** = Unknown (e-CRF Code **–997**)
NP = Not Palpable (e-CRF Code **–998**)	**NR** = Not Recorded/Not Done (e-CRF Code **–999**)	

PROPPR
Pragmatic, Randomized Optimal Platelet and Plasma Ratios

Study ID # ___ ___ ___ ___ ___ ___ ___

CONFIDENTIAL **(Bar Code)**

CRF Version Date: 2013 JUL 12 Completed By: ___ ___ ___

Form 1: Screening

Based on EMS/Trauma Alert Information & Site Policies, Pre-Order Randomized PROPPR MT Blood Products If Indicated*

1. ED Arrival: Date: __ __ /__ __ __ /__ __ (dd/mmm/yy) Time: __ __:__ __ (24hr Clock in hh:mm) ***(TIME ZERO)***

2 First available vital signs & GCS obtained after ED arrival:

Blood Pressure *(mmHg)*		Pulse *(beats/min)*	Temperature	Respiratory Rate
Systolic	Diastolic			
___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___ .___ ☐ F. ☐ C.	___ ___

GCS Record Component Scores **OR** GCS Total Score		Advanced Airway?	Chemically Paralyzed?
E: ___ V: ___ M: ___	GCS Total Score:___	☐ Yes ☐ No	☐ Yes ☐ No
☐ Not Recorded		☐ Unknown	☐ Unknown

3. Assessment of Blood Consumption (ABC) Score:

(Determined by Research Assistant Based on Initial Assessment on Arrival to Hospital/ED)

a. Penetrating Mechanism ☐ Yes (1) ☐ No (0) ☐ Unknown (0)

b. Systolic B/P ≤ 90 mmHg ☐ Yes (1) ☐ No (0) Time: _____:_____ *(24hr Clock in hh:mm)*

c. Pulse > 120 bpm ☐ Yes (1) ☐ No (0) Time: _____:_____ *(24hr Clock in hh:mm)*

d. FAST exam ☐ Positive (1) ☐ Negative (0) Time: _____:_____
☐ Indeterminate (0) ☐ Not Done (0) *(24hr Clock in hh:mm)*

Total ABC Score: ☐ **ZERO** ☐**1** ☐ **2** ☐ **3** ☐ **4**

4. Does ABC score predict patient will receive a MT?

☐ Yes *(ABC Score* **≥** *2,* ***Call*** *Blood Bank,* ***Process*** *TEG/Multiplate and continue to question #6)*

☐ No ***(HOLD*** *TEG/Multiplate Sample until further eligibility is determined and go to next question)*

5. Ask the Trauma Attending if a MT is needed: Time Answered: __ __:__ __ *(24hr Clock in hh:mm)*

☐ Yes Trauma Attending's Initials: ___ ___ ___
*(**Call** Blood Bank, **Process** TEG/Multiplate sample)*

☐ No *(Doesn't require MT. Patient is a screening failure.* ***Follow site policy on TEG/Multiplate analysis****.)*

****Patients with the 4th unit of RBC's spiked are ineligible for the PROPPR study****

Study ID # ___ ___ ___ ___ ___ ___ ___

CONFIDENTIAL **(Bar Code)**

CRF Version Date: 2013 JUL 12 Completed By: ___ ___ ___

Form 1: Screening *(cont.)*

6. First Available Blood Sample: **Check here** ☐ if the blood sample was not collected & proceed to next page. Document the reason for not collecting the sample on form # 22.

Blood Draw Time *(hh:mm)*	COAGs. *(Blue Top Sodium Citrate)*			R4 Blue 4.5 mL Citrate/Benzamidine	R5 Lavender 5 mL (FLOW for CORE Lab)
	R1 Blue 2.7 mL Tube *(Site TEG/Multiplate)*	**R2 Blue 4. 5 mL Tube**	**R3 Blue 4.5 mL Tube**		
:	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube
**Indicate if any problems occurred during collection	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**

Attach CRF Lab ID Label Here →

7. Will TEG/Multiplate lab values be reported with the first available blood sample?

☐Yes *(Record TEG/Multiplate values on form #14)* ☐ No

8. What site was used to collect the research blood sample? *(Select one)*

☐ Central Line ☐ Arterial Line ☐ Peripheral Vein

☐ Peripheral IV Line ☐ Other *(specify)*:_____ ☐ Unknown

9. Indicate the technique used to obtain the research blood sample.

☐ Syringe ☐ Vacutainer ☐ Unknown

10. Record the total I.V. fluids & blood products infused pre-hosp. to 1st blood sample collection:

Fluid/Blood Product	Amount Infused
Normal Saline	___ ___ ___ ___ ml.
Lactated Ringers	___ ___ ___ ___ ml.
Hypertonic Solution 3%	___ ___ ___ ___ ml.
Hypertonic Solution 5%	___ ___ ___ ___ ml.
Hypertonic Solution, other %, (specify):_____	___ ___ ___ ___ ml.
Plasma-Lyte	___ ___ ___ ___ ml.
Other Crystalloids, (specify):_____	___ ___ ___ ___ ml.
Albumin (5%)	___ ___ ___ ___ ml.
Albumin (25%)	___ ___ ___ ___ ml.
Hextend	___ ___ ___ ___ ml.
Hespan	___ ___ ___ ___ ml.
Other Colloids, (specify):_____	___ ___ ___ ___ ml.
RBCs	___ ___ Units
Plasma	___ ___ Units
Platelets	___ ___ Units

Research Blood Sample Collection Problem Codes: ***a*= excessive bleeding after venipuncture, ***b***=loss of vacuum during collection, ***c***=hematoma, ***d***= Other, (describe on form #22)*

Form 1: Screening *(cont.)*

11. Demographic Information:

a. Gender: ☐ Male
☐ Female
☐ Unknown

b. Year of Birth: ___ ___ ___ ___ □ Unknown
↓
If age is unknown, select the age group that best describes the subjects.
☐ Less than 15 years of age
☐ 15 to 19
☐ 20 to 34
☐ 35 to 49
☐ 50 to 65
☐ 65 years of age

c. Race/Ethnicity: *(Check all that apply)*

☐ White/non-Hispanic, non-Latino

☐ American Indian/Alaskan Native/Aboriginal

☐ Asian

☐ Black/African American

☐ Hispanic/Latino

☐ Native Hawaiian/other Pacific Islander

☐ Other *(Specify)*: _____

☐ Not Noted/Unknown

12. Subject height: __ __ __ . __ ☐ cm ☐ inches **Check here** ☐ if estimate

13. Subject weight: __ __ __ . __ ☐ kg ☐ pounds **Check here** ☐ if estimate

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Form 2: Verification of Eligibility

Inclusion Criteria: *(To be eligible, all questions must be answered "**YES**")*

1. Subject requires highest level of trauma activation	☐ Yes	☐ No
2. Age (Est. ≥ 15 yr. or ≥50 kg if age unknown)	☐ Yes	☐ No
3. Received directly from the injury scene	☐ Yes	☐ No
4. Received at least 1 unit of a blood component within the 1st hour after arrival or during pre-hospital transport	☐ Yes	☐ No
5. Predicted to receive a MT by exceeding the ABC threshold score or the Trauma Attending's judgment	☐ Yes	☐ No

Exclusion Criteria: *(To be eligible, all questions must be answered **"NO"**)*

1. Received care (defined as receiving a lifesaving intervention) from an outside hospital or healthcare facility	☐ Yes	☐ No
2. Moribund patient with devastating injury or expected to die within 1 hour of ED admission	☐ Yes	☐ No
3. Prisoners, defined as those who have been directly admitted from a correctional facility	☐ Yes	☐ No
4. Patients requiring an emergency thoracotomy (in ED)	☐ Yes	☐ No
5. Children under the age of 15yrs or under 50kg if age unknown	☐ Yes	☐ No
6. Known pregnancy in ED	☐ Yes	☐ No
7. Burns > 20% TBSA	☐ Yes	☐ No
8. Suspected inhalation injury	☐ Yes	☐ No
9. CPR (chest compressions for > 5 consecutive minutes) in the pre-arrival or ED setting	☐ Yes	☐ No
10. Known Do Not Resuscitate (DNR) prior to randomization	☐ Yes	☐ No
11. Enrolled in another concurrent, ongoing interventional, randomized clinical trial	☐ Yes	☐ No
12. Patients who have activated the "opt out" process or patients Legally Authorized Representatives that refuse blood products on arrival to ED.	☐ Yes	☐ No

Procedural Criteria: *(To be eligible, must be answered **"NO"**)*

1. At time of eligibility assessment, the 4th unit of RBC's was spiked.	☐ Yes	☐ No

Patient Eligibility Verified by:

_____ _____ _____:_____

Print Name *Signature* *(24hr Clock in hh:mm)*

Form 3: EMS / Pre-Hospital Care

1. EMS call date: __ __/__ __ __/__ __, ☐ NA, EMS Not Used *(Go to question #5 below)*
   (dd/mmm/yy)

2. EMS call/dispatch time: ____:____ ☐ Not Noted/Unknown
   (24hr Clock in hh:mm)

3. EMS arrival at scene: ____:____ ☐ Not Noted/Unknown
   (24hr Clock in hh:mm)

4. First available vital signs & GCS obtained by EMS at the scene:

Blood Pressure *(mmHg)*		Pulse *(beats/min)*	Temperature	Respiratory Rate
Systolic	Diastolic			
___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___ .___ ☐ F ☐ C	___ ___

GCS		Advanced Airway?	Chemically Paralyzed?
Record Component Scores **OR** GCS Total Score			
E: ___ V: ___ M: ___	GCS Total Score:___	☐ Yes ☐ No	☐ Yes ☐ No
☐ Not Recorded		☐ Unknown	☐ Unknown

5. Method of arrival to hospital: *(Select one)*

   ☐ Ambulance ☐ Helicopter/Air Transport ☐ Private Vehicle
   ☐ Walk in ☐ Other, describe: _____

6. Mechanism of Injury: (*As ascertained by EMS*)

   a. ☐ **Blunt Injury** *(Select all that apply)*
   - □ Fall
   - □ Machinery
   - □ MVC – Occupant
   - □ Motorcycle
   - □ MVC – Motorcycle
   - □ MVC – Bicycle
   - □ MVC – Pedestrian
   - □ Other, *(Describe)*:_____
   - □ MVC – Unknown
   - □ Struck by/against (assault)
   - □ Bicycle

   b. ☐ **Penetrating Injury** *(Select all that apply)*
   - □ Gunshot Wound
   - □ Stabbing (knife)
   - □ Shotgun Wound
   - □ Other, (*Describe*): _____
   - □ Impalement

7. Did the subject receive any pre-hospital lifesaving interventions?

   ☐ Yes, (*Select all that apply*) ☐ No
   - □ Cardioversion
   - □ Intubation
   - □ Chest/Needle Decompression
   - □ Trach/Cricothyrotomy
   - □ CPR
   - □ Tourniquet

Form 3: EMS / Pre-Hospital Care *(continued)*

8. IV fluids and/or blood products given before ED arrival:

Record total volume infused, **or check here** ☐ if no IV fluids/blood products were given.

Fluid/Blood Product	Amount Infused
Normal Saline	___ ___ ___ ___ ml.
Lactated Ringers	___ ___ ___ ___ ml.
Hypertonic Solution 3%	___ ___ ___ ___ ml.
Hypertonic Solution 5%	___ ___ ___ ___ ml.
Hypertonic Solution, other %, *(Specify)*:_____	___ ___ ___ ___ ml.
Plasma-Lyte	___ ___ ___ ___ ml.
Other Crystalloids, *(Specify)*:_____	___ ___ ___ ___ ml.
Albumin (5%)	___ ___ ___ ___ ml.
Albumin (25%)	___ ___ ___ ___ ml.
Hextend	___ ___ ___ ___ ml.
Hespan	___ ___ ___ ___ ml.
Other Colloids, *(Specify)*:_____	___ ___ ___ ___ ml.
RBCs	___ ___ Units
Plasma	___ ___ Units
Platelets	___ ___ Units

9. Procoagulants given before ED arrival?

Record total dose, **or check here** ☐ if no procoagulant were given before ED arrival.

Prothrombin Complex Concentrate *(PCC)*	Dose: ___ ___ ___ *(Specify Unit of Measure:_____)*
Tranexamic Acid *(Cyclokapron)*	Dose: ___ ___ ___ *(mg/kg/hr.)*
Other Procoagulant, *(Specify)*:_____	Dose: ___ ___ ___ *(Specify Unit of Measure:_____)*

Form 4: Randomization

1. Were PROPPR MT blood products ordered?

a. ☐ Yes ☐ No → *Reason?* ☐ Subject Died ☐ PROPPR Blood Products Not Available
↓ ☐ Other: _____

b. Time Blood Bank Notified of 1st PROPPR MT Order: __ __:__ __
↓ *(24hr Clock in hh:mm)*

c. Time 1st PROPPR Blood Products Received at the bedside: __ __:__ __
(24hr Clock in hh:mm)

2. Was the seal broken on PROPPR blood transport container?

a. ☐ Yes ☐ No →*Reason?*
- □ Subject Died
- □ Subject Improved, MT not needed
- □ Further Care Futile
- □ Screening failure, no PROPPR MT products were given within the 2hr window from admission.
- □ Screening failure, received 4 or more units of RBCs before subject could be randomized into the PROPPR study.
- □ Physician refused to randomize subject.
- □ Other, *(Specify)*: _____

b. Date: __ __ /__ __ __ /__ __ Time: ____:____
(dd/mmm/yy) *(24hr Clock in hh:mm)*

c. Randomization Number:

Record or Attach the Randomization Number Provided by Blood Bank Here

___ ___ ___ ___ ___ ___

3. Were PROPPR MT blood products transfused? (*If "**NO**" is selected for any reason, check the box at the beginning of form #7 to indicate there is no end of resuscitation data to record.*)

☐ Yes ☐ No → *Reason?*
- □ Subject Died
- □ Subject Improved, MT not needed
- □ Further Care Futile
- □ LAR Declined (*Document on forms 19 &/or 20*)

4. Where was PROPPR MT protocol started? *(Select one)*

☐ ED ☐ OR ☐ IR ☐ ICU ☐ Intermediate Level Care
☐ Nursing Unit ☐ Other, *(Specify)*:_____

PROPPR

Study ID # ___ ___ ___ ___ ___ ___ ___

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Form 5: Initial 24hr Vital Signs & Glasgow Coma Scale (GCS)

(Record initial vital signs & GCS at ***each location*** *or change of location during the first 24 hrs. of hospitalization. Print additional pages if needed.)*

Location (LOCAT) Codes	
1	Emergency Department
2	Operating Room
3	Interventional Radiology
4	ICU
5	Intermediate Level Care
6	Nursing Unit
7	Other *(Specify)*

GCS Scoring Key

Eye Movement (E)			**Verbal (V)**			**Motor (M)**		
	1	No Response		1	No Response / Intubated		1	No Response
	2	To Pain		2	Incomprehensible Sounds		2	Extension *(Decerebrate)*
	3	To Verbal Command		3	Inappropriate Words		3	Flexion – *(Decorticate)*
	4	Spontaneous		4	Disoriented, Converses		4	Flexion – Withdrawals From Pain
				5	Oriented, Converses		5	Localizes Pain
							6	Obeys Commands Appropriately

** Initial ED arrival vitals and GCS are recorded on Form 1. Record only vitals and GCS associated with transfer **BACK** to the ED.**

LOCAT Code	Date *(dd/mmm/yy)*	Time *(hh:mm)*	Blood Pressure *(mmHg)* Systolic	Diastolic	Pulse *(beats/min)*	Temperature	Advanced Airway ?	Chemically Paralyzed?	Respiratory Rate	GCS Record EVM Scores OR GCS Total Score
	/ /	:	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___.___ ☐ F ☐ C	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	___ ___	E: ___ or GCS V: ___ Total:____ M: ___
	/ /	:	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___.___ ☐ F ☐ C	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	___ ___	E: ___ or GCS V: ___ Total:____ M: ___
	/ /	:	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___.___ ☐ F ☐ C	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	___ ___	E: ___ or GCS V: ___ Total:____ M: ___
	/ /	:	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___.___ ☐ F ☐ C	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	___ ___	E: ___ or GCS V: ___ Total:____ M: ___
	/ /	:	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___.___ ☐ F ☐ C	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	___ ___	E: ___ or GCS V: ___ Total:____ M: ___
	/ /	:	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___.___ ☐ F ☐ C	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	___ ___	E: ___ or GCS V: ___ Total:____ M: ___
	/ /	:	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___.___ ☐ F ☐ C	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	___ ___	E: ___ or GCS V: ___ Total:____ M: ___
	/ /	:	___ ___ ___	___ ___ ___	___ ___ ___	___ ___ ___.___ ☐ F ☐ C	☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown	___ ___	E: ___ or GCS V: ___ Total:____ M: ___

PROPPR

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Form 6: IV Fluids & Blood Products Transfusion Record

*(Record blood products in **units** and all other fluids in **mL.s** using the **codes** below. Print additional pages if needed.)*

Location (LOCAT) Codes	
1	Emergency Department
2	Operating Room
3	Interventional Radiology
4	ICU
5	Intermediate Level Care
6	Nursing Unit
7	Other: *(Specify)*

Blood Products Codes			
1	Red Blood Cells (**RBC**)	7	Platelets - Pooled (**Plt-P**)
2	Plasma – Fresh Frozen (**FFP**)	8	Cryoprecipitate - (**Cryo**)
3	Plasma – Liquid (**LP**)	9	Autologous Blood (**Auto**)
4	Plasma - Thawed (**TP**)	10	Cell Saver - (**Cell**)
5	Plasma – FP24 (**FP24**)	11	Other Blood Product (**OBL**)
6	Platelets - Apheresis (**Plt -A**)		

MR: Data Collected from Medical Record Review	**DO:** Direct Observation

Colloids Codes		Crystalloids Codes	
1	Albumin (**Alb**)	6	Hypertonic Solution (**Ht**)
2	Hextend (**Hex**)	7	Lactated Ringers (**LR**)
3	Hespan (**Hes**)	8	Manitol (**MN**)
4	THAM Solution (THAM)	9	Normal Saline (**NS**)
5	Voluven (**Vol**)	10	Normosol (**Norm**)
		11	Plasma-Lyte (**PL**)
12	**Other Colloid (OCL) or Crystalloid (OCY)**		
****Document any deviations from MT protocol on form #22. ****			

****Complete for All Blood Products & IV Fluids****							****Complete for ONLY Blood Products****				
LOCAT Code	Blood / Fluid Code	Start Date *(dd/mmm/yy)*	Start Time *(hh:mm)*	Amount Given		DO MR	Random Aphaeresis	Type Specific	Cross-Matched	Unit or Accession #	Product Given At What Time Point?
		/ /	:	____	☐ Units ☐ ml.	☐ DO ☐ MR	☐ Aphaeresis ☐ Leuko-reduced ☐ NA ☐ NK ☐ Pooled ☐ Random	☐ Yes ☐ No ☐ NA ☐ NK	☐ Yes ☐ No ☐ NA ☐ NK	 Exp. Date: / /	☐ Pre-Randomization ☐ Randomized → Last Unit Given? ☐ Yes ☐ No ☐ Post-Randomization ☐ Not Noted/Unknown
		/ /	:	____	☐ Units ☐ ml.	☐ DO ☐ MR	☐ Aphaeresis ☐ Leuko-reduced ☐ NA ☐ NK ☐ Pooled ☐ Random	☐ Yes ☐ No ☐ NA ☐ NK	☐ Yes ☐ No ☐ NA ☐ NK	 Exp. Date: / /	☐ Pre-Randomization ☐ Randomized → Last Unit Given? ☐ Yes ☐ No ☐ Post-Randomization ☐ Not Noted/Unknown
		/ /	:	____	☐ Units ☐ ml.	☐ DO ☐ MR	☐ Aphaeresis ☐ Leuko-reduced ☐ NA ☐ NK ☐ Pooled ☐ Random	☐ Yes ☐ No ☐ NA ☐ NK	☐ Yes ☐ No ☐ NA ☐ NK	 Exp. Date: / /	☐ Pre-Randomization ☐ Randomized → Last Unit Given? ☐ Yes ☐ No ☐ Post-Randomization ☐ Not Noted/Unknown
		/ /	:	____	☐ Units ☐ ml.	☐ DO ☐ MR	☐ Aphaeresis ☐ Leuko-reduced ☐ NA ☐ NK ☐ Pooled ☐ Random	☐ Yes ☐ No ☐ NA ☐ NK	☐ Yes ☐ No ☐ NA ☐ NK	 Exp. Date: / /	☐ Pre-Randomization ☐ Randomized → Last Unit Given? ☐ Yes ☐ No ☐ Post-Randomization ☐ Not Noted/Unknown
		/ /	:	____	☐ Units ☐ ml.	☐ DO ☐ MR	☐ Aphaeresis ☐ Leuko-reduced ☐ NA ☐ NK ☐ Pooled ☐ Random	☐ Yes ☐ No ☐ NA ☐ NK	☐ Yes ☐ No ☐ NA ☐ NK	 Exp. Date: / /	☐ Pre-Randomization ☐ Randomized → Last Unit Given? ☐ Yes ☐ No ☐ Post-Randomization ☐ Not Noted/Unknown
		/ /	:	____	☐ Units ☐ ml.	☐ DO ☐ MR	☐ Aphaeresis ☐ Leuko-reduced ☐ NA ☐ NK ☐ Pooled ☐ Random	☐ Yes ☐ No ☐ NA ☐ NK	☐ Yes ☐ No ☐ NA ☐ NK	 Exp. Date: / /	☐ Pre-Randomization ☐ Randomized → Last Unit Given? ☐ Yes ☐ No ☐ Post-Randomization ☐ Not Noted/Unknown

Form 7: End of Resuscitation / PROPPR Protocol Treatment

Check here ☐ if no randomized blood products were given. *(i.e. the subject improved or died.)*

1. Source of bleeding requiring the transfusion: *(Select all that apply)*

☐ Abdomen ☐ Chest ☐ Intracranial ☐ Limb/Extremity ☐ Neck

☐ Pelvis ☐ Scalp/Face ☐ Not Noted/Unknown

2. PROPPR MT protocol stop date: __ __/__ __ __/__ __ Time: _____:_____
(dd/mmm/yy) *(24hr Clock in hh:mm)*

3. Why was the PROPPR MT protocol stopped? *(Select one)*

☐ Trauma Attending and/or Anesthesiologist determined subject was no longer bleeding, and adequately resuscitated.

a. Anatomic Hemostasis Time: **_____:_____** ☐ Actual ☐ Estimate
(24hr Clock in hh:mm)

Check here ☐ to report additional hemostasis times, document information on form #22.

b. Active Resuscitation with
Blood Products Stop Time: **_____:_____** ☐ Actual ☐ Estimate
(24hr Clock in hh:mm,)

☐ Further transfusions were deemed futile and/or subject expired.
(Document death on CRF #18 and notify HDCC)

☐ Unable to achieve hemostasis.

☐ Early protocol stop per treating physician request. *(*RA's/Coordinators are required to notify Site PI*)*
Physician Name: _____ Reason: _____

☐ Randomized blood products became unavailable.

☐ Other, (specify): _____

4. Was the Blood Bank notified to stop PROPPR MT protocol?

☐ Yes ↓ ☐ No ☐ Not Noted/Unknown
Date: __ __/__ __ __/__ __, Time: _____:_____
(dd/mmm/yy) *(24hr Clock in hh:mm)*

5. Location of subject at the end of resuscitation period: *(Select one)*

☐ ED ☐ OR ☐ IR ☐ ICU ☐ Intermediate Level Care

☐ Nursing Unit ☐ Other, specify: _____

6. Did the subject have an unstable pelvic fracture by manual compression? ☐ Yes ↓ ☐ No ☐ Not Noted/Unknown
Discovered on:
Date: __ __/__ __ __/__ __ Time: _____:_____
(dd/mmm/yy) *(24hr Clock in hh:mm)*

7. Did the subject have an open femur fracture? ☐ Yes ↓ ☐ No ☐ Not Noted/Unknown
Discovered on:
Date: __ __/__ __ __/__ __ Time: _____:_____
(dd/mmm/yy *(24hr Clock in hh:mm)*

Form 8: Lifesaving Interventions *(Print additional pages if needed.)*

Check here ☐ if no lifesaving interventions were performed.

Location Codes (LOCAT)	
1	Emergency Department
2	Operating Room
3	Interventional Radiology
4	ICU
5	Intermediate Level Care
6	Nursing Unit
7	Other: *(Specify)*

Life Saving Interventions Codes	
1	Cardioversion
2	CPR
3	Emergency Laparotomy
4	Emergency Intubation
5	Chest Tube Insertion
6	Trach/Cricothyrotomy
7	Emergency Thoracotomy
8	Pericardiocentesis
9	Other *(Specify)*

LOCAT Code	Start Date *(dd/mmm/yy)*	Start Time *(hh:mm)*	Intervention Code
	/ /	:	
	/ /	:	
	/ /	:	
	/ /	:	
	/ /	:	
	/ /	:	
	/ /	:	
	/ /	:	
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	/ /	:	
	/ /	:	
	/ /	:	
	/ /	:	

Form 9: Procoagulant Medications *(Record individual doses, print additional pages if needed)*

Check here ☐ if no procoagulant medications were given.

LOCATION CODE (LOCAT)	
1	Emergency Department
2	Operating Room
3	Interventional Radiology
4	ICU
5	Intermediate Level Care
6	Nursing Unit
7	Other *(Specify)*

Document Administration of the Following Medications Using the Codes Below	
1	Aminocaproic Acid *(Amicar) (g/hr.)*
2	Tranexamic Acid *(Cyclokapron) (mg/kg/hr.)*
3	Fibrinogen Concentrate *(Riastap) (mg/kg/hr.)*
4	Octaplex / Ocplex *(in ml.s)*
5	Prothrombin Complex Concentrate *(PCC)*
6	Recombinant Factor VIIa *(rFVIIa) (mics/kg)*
7	Factor VIII
8	Vitamin K
9	OTHER Procoagulant *(Specify with unit of measure)*

LOCAT	Administration Start Date *(dd/mmm/yy)*	Administration Start Time *(24hr clock in hh:mm)*	Medication Code *(If other, Specify)*	Dose Given
	/ /	:		___ ___ ___
	/ /	:		___ ___ ___
	/ /	:		___ ___ ___
	/ /	:		___ ___ ___
	/ /	:		___ ___ ___
	/ /	:		___ ___ ___
	/ /	:		___ ___ ___
	/ /	:		___ ___ ___
	/ /	:		___ ___ ___
	/ /	:		___ ___ ___
	/ /	:		___ ___ ___
	/ /	:		___ ___ ___
	/ /	:		___ ___ ___
	/ /	:		___ ___ ___
	/ /	:		___ ___ ___

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Form 10: Operating Room (OR) Visits

Check here ☐ if there were no OR visits

(Document OR visits from admission through Day 30 by date using the codes below. For OR visits during the initial resuscitation, also complete form #15. Print additional pages as needed.)

Surgical Procedure Codes

Head		**Surgical &/or Endoscopic Procedures Involving:**		**Pelvic Procedures**		**Upper Extremity Procedures**		**Lower Extremity Procedures**	
1	Craniotomy								
2	Craniectomy								
3	Subdural/Epidural Hematoma								
Neck									
4	Exploration of Neck	**10**	Esophagus	**18**	Closed Reduction	**25**	Amputation through the Forearm	**32**	Below Knee Amputation
		11	Stomach						
Chest		**12**	Small Intestine	**19**	Open Reduction/Internal Fixation	**26**	Amputation through the Humerus	**33**	Above Knee Amputation
5	Thoracotomy	**13**	Large Intestine	**20**	External Fixation	**27**	External Fixation of the Humerus	**34**	Closed Reduction/Internal Fixation
Abdomen		**Solid Organ Procedures**		**Damage Control Procedures**		**28**	External Fixation of the Forearm	**35**	Open Reduction/Internal Fixation
6	Exploratory Laparotomy	**14**	Liver	**21**	Abdominal Packing	**29**	Open Reduction/Internal Fixation	**36**	External Fixation of Tibia
Major Vascular Procedures		**15**	Kidney	**22**	Thoracic Packing	**30**	Closed Reduction/Internal Fixation	**37**	External Fixation of Femur
7	Artery/Vein Repair	**16**	Spleen	**23**	Vascular Shunt	**31**	Fasciotomy for Compartment Syndrome	**38**	Fasciotomy for Compartment Syndrome
Other Surgical Procedures		**17**	Pancreas	**24**	Temporary Abdominal Closure	**OR**	**Interventional Radiology Procedures →**	**39**	All IR Procedures Performed in the OR
8	Irrigation/Debridement								
9	Other *(Specify of form #22)*:								

"Unplanned" OR visits are defined as emergent/urgent surgical procedures. An OR visit on the day of admission from the ED does not need to be recorded on the AE/SAE Form #18. All other unplanned OR visits should be recorded on Form #18.

Record date in dd/mmm/yy format, and time using 24 hr. clock in hh:mm

OR Visit	Date of OR Visit	OR Arrival Time	Type of Visit?	**Primary** Surgical Procedure Code	Additional Surgical Procedure Code	Additional Surgical Procedure Code	Additional Surgical Procedure Code	Additional Surgical Procedure Code	Additional Surgical Procedure Code	Additional Surgical Procedure Code
1	/ /	:	☐ Planned ☐ Unplanned	__ __	__ __	__ __	__ __	__ __	__ __	__ __
	/ /	:	☐ Planned ☐ Unplanned	__ __	__ __	__ __	__ __	__ __	__ __	__ __
	/ /	:	☐ Planned ☐ Unplanned	__ __	__ __	__ __	__ __	__ __	__ __	__ __
	/ /	:	☐ Planned ☐ Unplanned	__ __	__ __	__ __	__ __	__ __	__ __	__ __
	/ /	:	☐ Planned ☐ Unplanned	__ __	__ __	__ __	__ __	__ __	__ __	__ __
	/ /	:	☐ Planned ☐ Unplanned	__ __	__ __	__ __	__ __	__ __	__ __	__ __
	/ /	:	☐ Planned ☐ Unplanned	__ __	__ __	__ __	__ __	__ __	__ __	__ __
	/ /	:	☐ Planned ☐ Unplanned	__ __	__ __	__ __	__ __	__ __	__ __	__ __

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Form 11: Interventional Radiology (IR) Visit

Check here ☐ if there were no IR visits

(Document IR visits from admission through Day 30 by date using the codes below. For IR visits during the initial resuscitation, also complete form #15. Print additional pages as needed.)

Interventional Radiology Codes					
1	Craniocervical, Diagnostic	**6**	Hepatic, Therapeutic	**11**	Splenic, Diagnostic
2	Craniocervical, Therapeutic	**7**	Pelvic, Diagnostic	**12**	Splenic, Therapeutic
3	Extremity, Diagnostic	**8**	Pelvic, Therapeutic	**13**	Thoracoabdominal, Diagnostic
4	Extremity, Therapeutic	**9**	Renal, Diagnostic	**14**	Thoracoabdominal, Therapeutic
5	Hepatic, Diagnostic	**10**	Renal, Therapeutic	**15**	Other Angio Procedure: *(Describe on form # 22)*

IR Visit	Date of IR Visit *(dd/mmm/yy)*	IR Arrival Time *(24hr Clock in hh:mm)*	Type of Visit?	**Primary** IR Procedure Code	Additional IR Procedure Code	Additional IR Procedure Code	Additional IR Procedure Code	Additional IR Procedure Code	Additional IR Procedure Code
1	/ /	:	☐ Planned ☐ Unplanned	__ __	__ __	__ __	__ __	__ __	__ __
	/ /	:	☐ Planned ☐ Unplanned	__ __	__ __	__ __	__ __	__ __	__ __
	/ /	:	☐ Planned ☐ Unplanned	__ __	__ __	__ __	__ __	__ __	__ __
	/ /	:	☐ Planned ☐ Unplanned	__ __	__ __	__ __	__ __	__ __	__ __
	/ /	:	☐ Planned ☐ Unplanned	__ __	__ __	__ __	__ __	__ __	__ __
	/ /	:	☐ Planned ☐ Unplanned	__ __	__ __	__ __	__ __	__ __	__ __
	/ /	:	☐ Planned ☐ Unplanned	__ __	__ __	__ __	__ __	__ __	__ __
	/ /	:	☐ Planned ☐ Unplanned	__ __	__ __	__ __	__ __	__ __	__ __
	/ /	:	☐ Planned ☐ Unplanned	__ __	__ __	__ __	__ __	__ __	__ __
	/ /	:	☐ Planned ☐ Unplanned	__ __	__ __	__ __	__ __	__ __	__ __

Form 12: Initial 24 hrs. Clinical Lab Results

(Record the first available lab results for the following tests at each location or location change for the 1st 24 hrs. following admission)

LOCATION CODE (LOCAT)			
1	Emergency Department	**5**	Intermediate Level Care
2	Operating Room	**6**	Nursing Unit
3	Interventional Radiology	**7**	Other *(Specify)*
4	ICU		

Section A: Pregnancy Test & Blood Type

LOCAT CODE	Date *(dd/mmm/yy)*	Time *(hh:mm)*	Lab Test		Results	Not Done
	/ /	:	Pregnancy Test	□ Blood □ Urine	□ Positive □ Negative □ Indeterminate	☐
	/ /	:	Blood Type	□ A Positive □ A Negative □ B Positive □ B Negative □ AB Positive □ AB Negative □ O Positive □ O Negative		☐

Section B: Blood Count & Coagulation Tests

***Indicate unit of measure, then enter value in the table below:**

Hgb? □ mmol/L □ g/dL □ g/L □ Other *(Specify)*:	**Fibrinogen?** □ mg/dL □ g/L □ Other *(Specify)*:	**Platelets?** □ x 10^3/µL □ x 10^9/L □ x 10^3/ ml^3 □ Other *(Specify)*:	**WBC?** □ x 10^3/µL □ x 10^9/L □ x 10^3/ mm^3 □ Other *(Specify)*:

LOCAT CODE	Date *(dd/mmm/yy)*	Time *(hh:mm)*	*Hgb	Hct %	*Platelets	*WBC	PT *(sec)*	PTT *(sec)*	INR	*Fibrinogen
	/ /	:	.	.	.	.	.	.	.	.
	/ /	:	.	.	.	.	.	.	.	.
	/ /	:	.	.	.	.	.	.	.	.
	/ /	:	.	.	.	.	.	.	.	.
	/ /	:	.	.	.	.	.	.	.	.
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(Print additional pages as needed.)

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Form 12: Initial 24hrs. Clinical Lab Results *(cont.)*

(Record the first available lab results for the following tests at each location or location change for the 1st 24 hrs. following admission)

LOCATION CODE (LOCAT)			
1	Emergency Department	**5**	Intermediate Level Care
2	Operating Room	**6**	Nursing Unit
3	Interventional Radiology	**7**	Other *(Specify)*
4	ICU		

Section C: Blood Gases

***Indicate unit of measure, then enter value in the table below:**

CO_2? □ mmol/L □ mg/L □ mEq/L □ Other *(Specify)*:

HCO_3? □ mmol/L □ mg/L □ Other *(Specify)*:

LOCAT CODE	Date *(dd/mmm/yy)*	Time *(hh:mm)*	Type of Blood Sample	FiO_2 %	pH	PaO_2 (mmHg)	$PaCO_2$ (mmHg)	*CO_2	*HCO_3	SaO_2 %	Base (mmol/L)	
	/ /	:	□ Arterial □ Venous									□ Deficit □ Excess
	/ /	:	□ Arterial □ Venous									□ Deficit □ Excess
	/ /	:	□ Arterial □ Venous									□ Deficit □ Excess
	/ /	:	□ Arterial □ Venous									□ Deficit □ Excess
	/ /	:	□ Arterial □ Venous									□ Deficit □ Excess
	/ /	:	□ Arterial □ Venous									□ Deficit □ Excess
	/ /	:	□ Arterial □ Venous									□ Deficit □ Excess
	/ /	:	□ Arterial □ Venous									□ Deficit □ Excess
	/ /	:	□ Arterial □ Venous									□ Deficit □ Excess
	/ /	:	□ Arterial □ Venous									□ Deficit □ Excess
	/ /	:	□ Arterial □ Venous									□ Deficit □ Excess
	/ /	:	□ Arterial □ Venous									□ Deficit □ Excess
	/ /	:	□ Arterial □ Venous									□ Deficit □ Excess
	/ /	:	□ Arterial □ Venous									□ Deficit □ Excess

(Print additional pages as needed.)

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Form 12: Initial 24hrs. Clinical Lab Results *(cont.)*

(Record the first available lab results for the following tests at each location or location change for the 1st 24 hrs. following admission)

LOCATION CODE (LOCAT)			
1	Emergency Department	5	Intermediate Level Care
2	Operating Room	6	Nursing Unit
3	Interventional Radiology	7	Other *(Specify)*
4	ICU		

Section D: Chemistry & Metabolic Panels

*** Indicate unit of measure, then enter value in the table below:**

Lactate? □ mg/dL □ mEq/L □ mmol/L □ Other *(Specify):* **Creatinine?** □ mg/dL □ µmol/L □ Other *(Specify):* **Glucose?** □ mg/dL □ mmol/L □ Other *(Specify):*

Albumin? □ g/L □ U/L □ µmol/L □ g/dL □ Other *(Specify):* **Total Bilirubin?** □ mg/dL □ µmol/L □ Other *(Specify):*

LOCAT CODE	Date *(dd/mmm/yy)*	Time *(hh:mm)*	Sodium *(mEq/L)*	Potassium *(mEq/L)*	Chloride *(mEq/L)*	*Lactate	BUN *(mg/dL)*	*Creatinine	*Glucose	*Albumin	*Total Bilirubin	Bilirubin Direct, *(mg/dL)*	Bilirubin Indirect *(mg/dL)*	Calcium *(mg/dL)*
	/ /	:	.	.	.	______ □ Arterial □ Venous	.	.	.		.	.	.	.
	/ /	:	.	.	.	______ □ Arterial □ Venous	.	.	.		.	.	.	.
	/ /	:	.	.	.	______ □ Arterial □ Venous	.	.	.		.	.	.	.
	/ /	:	.	.	.	______ □ Arterial □ Venous	.	.	.		.	.	.	.
	/ /	:	.	.	.	______ □ Arterial □ Venous	.	.	.		.	.	.	.
	/ /	:	.	.	.	______ □ Arterial □ Venous	.	.	.		.	.	.	.
	/ /	:	.	.	.	______ □ Arterial □ Venous	.	.	.		.	.	.	.
	/ /	:	.	.	.	______ □ Arterial □ Venous	.	.	.		.	.	.	.
	/ /	:	.	.	.	______ □ Arterial □ Venous	.	.	.		.	.	.	.
	/ /	:	.	.	.	______ □ Arterial □ Venous	.	.	.		.	.	.	.
	/ /	:	.	.	.	______ □ Arterial □ Venous	.	.	.		.	.	.	.
	/ /	:	.	.	.	______ □ Arterial □ Venous	.	.	.		.	.	.	.
	/ /	:	.	.	.	______ □ Arterial □ Venous	.	.	.		.	.	.	.

(Print additional pages as needed.)

Form 13: PROPPR Research Blood Samples

Use this form to record research blood samples collected from **randomized** subjects after the first available blood sample. **Check here** ☐ if subject **died** before the 2 hour blood sample was collected, *(form is complete, proceed to the next form)*. Provide explanation for blood samples collected outside the time window on form #22.

Section A: 2 hour Research Blood Sample

Check here ☐ if the 2 hour research blood sample was not collected *(missed).*

1. Research Blood Sample Collection Date: ___ ___ / ___ ___ ___ / ___ ___
(dd/mmm/yy)

2. Research Blood Sample Collection Time: ___ ___ : ___ ___
(24hr Clock in hh:mm)

3. Record the collection information in the table below.

	COAGs. *(Blue Top Sodium Citrate)*			**R4 Blue 4.5 mL Citrate/Benzamidine**	**R5 Lavender 5 mL (FLOW for CORE Lab)**
	R1 Blue 2.7 mL Tube *(Site TEG/Multiplate)*	**R2 Blue 4. 5 mL Tube**	**R3 Blue 4.5 mL Tube**		
	☐ Not Collected ☐ 1/3 Tube ☐ 1/2 Tube ☐ Full Tube	☐ Not Collected ☐ 1/3 Tube ☐ 1/2 Tube ☐ Full Tube	☐ Not Collected ☐ 1/3 Tube ☐ 1/2 Tube ☐ Full Tube	☐ Not Collected ☐ 1/3 Tube ☐ 1/2 Tube ☐ Full Tube	☐ Not Collected ☐ 1/3 Tube ☐ 1/2 Tube ☐ Full Tube
****Indicate if any problems occurred during collection**	☐ **Yes** (check problem code) ☐ a ☐ b ☐ c ☐ d ☐ **No**	☐ **Yes** (check problem code) ☐ a ☐ b ☐ c ☐ d ☐ **No**	☐ **Yes** (check problem code) ☐ a ☐ b ☐ c ☐ d ☐ **No**	☐ **Yes** (check problem code) ☐ a ☐ b ☐ c ☐ d ☐ **No**	☐ **Yes** (check problem code) ☐ a ☐ b ☐ c ☐ d ☐ **No**
Attach CRF Lab ID Label Here →					

4. What site was used to collect the research blood sample? *(Select one)*

☐ Central Line ☐ Arterial Line ☐ Peripheral Vein

☐ Peripheral IV Line ☐ Other *(specify)*:_____ ☐ Unknown

5. Indicate the technique used to obtain the research blood sample.

☐ Syringe ☐ Vacutainer ☐ Unknown

***Research Blood Sample Collection Problem Codes: **a**= excessive bleeding after venipuncture, **b**=loss of vacuum during collection, **c**=hematoma, **d**= Other, (describe on form #22)*

Form 13: PROPPR Research Blood Samples *(cont.)*

Section B: 4 hour Research Blood Sample

Check here ☐ if the 4 hour research blood sample was not collected *(missed).*

1. Research Blood Sample Collection Date: ___ ___ / ___ ___ ___ / ___ ___
(dd/mmm/yy)

2. Research Blood Sample Collection Time: ___ ___ : ___ ___
(24hr Clock in hh:mm)

3. Record the collection information in the table below.

	COAGs. *(Blue Top Sodium Citrate)*			**R4 Blue 4.5 mL Citrate/Benzamidine**	**R5 Lavender 5 mL** (FLOW for CORE Lab)
	R1 Blue 2.7 mL Tube *(Site TEG/Multiplate)*	**R2 Blue 4. 5 mL Tube**	**R3 Blue 4.5 mL Tube**		
	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube
****Indicate if any problems occurred during collection**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**
Attach CRF Lab ID Label Here →					

4. What site was used to collect the research blood sample? *(Select one)*

☐ Central Line ☐ Arterial Line ☐ Peripheral Vein
☐ Peripheral IV Line ☐ Other *(specify)*:_____ ☐ Unknown

5. Indicate the technique used to obtain the research blood sample.

☐ Syringe ☐ Vacutainer ☐ Unknown

******Research Blood Sample Collection Problem Codes:* ***a****= excessive bleeding after venipuncture,* ***b****=loss of vacuum during collection,* ***c****=hematoma,* ***d****= Other, (describe on form #22)*

Form 13: PROPPR Research Blood Samples *(cont.)*

Section C: 6 hour Research Blood Sample

Check here ☐ if the 6 hour research blood sample was not collected *(missed)*.

1. Research Blood Sample Collection Date: ___ ___ / ___ ___ ___ / ___ ___
(dd/mmm/yy)

2. Research Blood Sample Collection Time: ___ ___ : ___ ___
(24hr Clock in hh:mm)

3. Record the collection information in the table below.

	COAGs. *(Blue Top Sodium Citrate)*			R4 Blue 4.5 mL Citrate/Benzamidine	R5 Lavender 5 mL (FLOW for CORE Lab)
	R1 Blue 2.7 mL Tube *(Site TEG/Multiplate)*	**R2 Blue 4. 5 mL Tube**	**R3 Blue 4.5 mL Tube**		
	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube
****Indicate if any problems occurred during collection**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**
Attach CRF Lab ID Label Here →					

4. What site was used to collect the research blood sample? *(Select one)*

☐ Central Line ☐ Arterial Line ☐ Peripheral Vein
☐ Peripheral IV Line ☐ Other *(specify)*:_____ ☐ Unknown

5. Indicate the technique used to obtain the research blood sample.

☐ Syringe ☐ Vacutainer ☐ Unknown

******Research Blood Sample Collection Problem Codes:* ***a****= excessive bleeding after venipuncture,* ***b****=loss of vacuum during collection,* ***c****=hematoma,* ***d****= Other, (describe on form #22)*

Form 13: PROPPR Research Blood Samples *(cont.)*

Section D: 12 hour Research Blood Sample

Check here ☐ if the 12 hour research blood sample was not collected *(missed)*.

1. Research Blood Sample Collection Date: ___ ___ / ___ ___ ___ / ___ ___
(dd/mmm/yy)

2. Research Blood Sample Collection Time: ___ ___ : ___ ___
(24hr Clock in hh:mm)

3. Record the collection information in the table below.

	COAGs. *(Blue Top Sodium Citrate)*			**R4 Blue 4.5 mL Citrate/Benzamidine**	**R5 Lavender 5 mL (FLOW for CORE Lab)**
	R1 Blue 2.7 mL Tube *(Site TEG/Multiplate)*	**R2 Blue 4. 5 mL Tube**	**R3 Blue 4.5 mL Tube**		
	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube
****Indicate if any problems occurred during collection**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**
Attach CRF Lab ID Label Here →					

4. What site was used to collect the research blood sample? *(Select one)*

☐ Central Line ☐ Arterial Line ☐ Peripheral Vein
☐ Peripheral IV Line ☐ Other *(specify)*:_____ ☐ Unknown

5. Indicate the technique used to obtain the research blood sample.

☐ Syringe ☐ Vacutainer ☐ Unknown

******Research Blood Sample Collection Problem Codes: **a**= excessive bleeding after venipuncture, **b**=loss of vacuum during collection, **c**=hematoma, **d**= Other, (describe on form #22)*

Form 13: PROPPR Research Blood Samples *(cont.)*

Section E: 24 hour Research Blood Sample

Check here ☐ if the 24 hour research blood sample was not collected *(missed).*

1. Research Blood Sample Collection Date: ___ ___ / ___ ___ ___ / ___ ___
(dd/mmm/yy)

2. Research Blood Sample Collection Time: ___ ___ : ___ ___
(24hr Clock in hh:mm)

3. Record the collection information in the table below.

	COAGs. *(Blue Top Sodium Citrate)*			**R4 Blue 4.5 mL Citrate/Benzamidine**	**R5 Lavender 5 mL** (FLOW for CORE Lab)
	R1 Blue 2.7 mL Tube *(Site TEG/Multiplate)*	**R2 Blue 4. 5 mL Tube**	**R3 Blue 4.5 mL Tube**		
	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube
****Indicate if any problems occurred during collection**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**
Attach CRF Lab ID Label Here →					

4. What site was used to collect the research blood sample? *(Select one)*

☐ Central Line ☐ Arterial Line ☐ Peripheral Vein
☐ Peripheral IV Line ☐ Other *(specify)*:_____ ☐ Unknown

5. Indicate the technique used to obtain the research blood sample.

☐ Syringe ☐ Vacutainer ☐ Unknown

******Research Blood Sample Collection Problem Codes: **a**= excessive bleeding after venipuncture, **b**=loss of vacuum during collection, **c**=hematoma, **d**= Other, (describe on form #22)*

Form 13: PROPPR Research Blood Samples *(cont.)*

Section F: 48 hour Research Blood Sample

Check here ☐ if the 48 hour research blood sample was not collected *(missed).*

1. Research Blood Sample Collection Date: ___ ___ / ___ ___ ___ / ___ ___
(dd/mmm/yy)

2. Research Blood Sample Collection Time: ___ ___ : ___ ___
(24hr Clock in hh:mm)

3. Record the collection information in the table below.

	COAGs. *(Blue Top Sodium Citrate)*			R4 Blue 4.5 mL Citrate/Benzamidine	R5 Lavender 5 mL (FLOW for CORE Lab)
	R1 Blue 2.7 mL Tube *(Site TEG/Multiplate)*	**R2 Blue 4. 5 mL Tube**	**R3 Blue 4.5 mL Tube**		
	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube
****Indicate if any problems occurred during collection**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**
Attach CRF Lab ID Label Here →					

4. What site was used to collect the research blood sample? *(Select one)*

☐ Central Line ☐ Arterial Line ☐ Peripheral Vein
☐ Peripheral IV Line ☐ Other *(specify)*:_____ ☐ Unknown

5. Indicate the technique used to obtain the research blood sample.

☐ Syringe ☐ Vacutainer ☐ Unknown

Research Blood Sample Collection Problem Codes:* ***a*= excessive bleeding after venipuncture,* ***b****=loss of vacuum during collection,* ***c****=hematoma,* ***d****= Other, (describe on form #22)*

Form 13: PROPPR Research Blood Samples *(cont.)*

Section G: 72 hour Research Blood Sample

Check here ☐ if the 72 hour research blood sample was not collected *(missed).*

1. Research Blood Sample Collection Date: ___ ___ / ___ ___ ___ / ___ ___
dd/mmm/yy)

2. Research Blood Sample Collection Time: ___ ___ : ___ ___
(24hr Clock in hh:mm)

3. Record the collection information in the table below.

	COAGs. *(Blue Top Sodium Citrate)*			**R4 Blue 4.5 mL Citrate/Benzamidine**	**R5 Lavender 5 mL (FLOW for CORE Lab)**
	R1 Blue 2.7 mL Tube *(Site TEG/Multiplate)*	**R2 Blue 4. 5 mL Tube**	**R3 Blue 4.5 mL Tube**		
	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube	□ Not Collected □ 1/3 Tube □ 1/2 Tube □ Full Tube
****Indicate if any problems occurred during collection**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**	□ **Yes** (check problem code) □ a □ b □ c □ d □ **No**
Attach CRF Lab ID Label Here →					

4. What site was used to collect the research blood sample? *(Select one)*

☐ Central Line ☐ Arterial Line ☐ Peripheral Vein
☐ Peripheral IV Line ☐ Other *(specify)*:_____ ☐ Unknown

5. Indicate the technique used to obtain the research blood sample.

☐ Syringe ☐ Vacutainer ☐ Unknown

******Research Blood Sample Collection Problem Codes: **a**= excessive bleeding after venipuncture, **b**=loss of vacuum during collection, **c**=hematoma, **d**= Other, (describe on form #22)*

Form 14: PROPPR Research Blood Sample TEG and Multiplate Results

Use this form to record research blood sample TEG and Multiplate results. **Check here** ☐ if the subject died before any research blood samples could be obtained. The 2 hour and beyond TEG/Multiplate tests should only be performed on **randomized** subjects.

Section A: TEG Results

Sample Time Point		Date / Start Time	*Split Point (min.)*	R-Time *(min.)*	K-Time *(min.)*	Alpha Angle (%)	Max. Amp. *(mm)*	G-Value *(d/sc)*	Ly30 (%)	Ly60 (%)	TMRTG	MRTG	TG
1st Available (Time Zero)	□ Done □ Not Done	/ / :	.	.	.	.	.	.	.	.	.	.	.
2 hour	□ Done □ Not Done	/ / :	.	.	.	.	.	.	.	.	.	.	.
4 hour	□ Done □ Not Done	/ / :	.	.	.	.	.	.	.	.	.	.	.
6 hour	□ Done □ Not Done	/ / :	.	.	.	.	.	.	.	.	.	.	.
12 hour	□ Done □ Not Done	/ / :	.	.	.	.	.	.	.	.	.	.	.
24 hour	□ Done □ Not Done	/ / :	.	.	.	.	.	.	.	.	.	.	.
48 hour	□ Done □ Not Done	/ / :	.	.	.	.	.	.	.	.	.	.	.
72 hour	□ Done □ Not Done	/ / :	.	.	.	.	.	.	.	.	.	.	.

TEG/Multiplate Lab ID Labels

Apply 1st Available Lab ID Label Here	Apply 2 hr Lab ID Label Here	Apply 4 hr Lab ID Label Here	Apply 6 hr Lab ID Label Here
Apply 12 hr Lab ID Label Here	Apply 24 hr Lab ID Label Here	Apply 48 hr Lab ID Label Here	Apply 72 hr Lab ID Label Here

Form 14: PROPPR Research Blood Sample TEG and Multiplate Results *(cont.)*

Section B: Multiplate Results

Sample Time Point		Date / Start Time	*ADP AUC (U)*	ADP AG(AU)	*ADP VEL (AU/min)*	COL AUC (U)	COL AG (AU)	COL VEL (AU/min)	TRAP AUC (U)	TRAP AG (AU)	*TRAP VEL (AU/min)*	*ASPI AUC (U)*	ASPI AG (AU)	ASPI VEL (AU/min)	RISTO AUC (U)	RISTO AG (AU)	RISTO VEL (AU/min)
1st Ave Time Zero	□ Done □ Not Done	/ / :	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
2 hour	□ Done □ Not Done	/ / :	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
4 hour	□ Done □ Not Done	/ / :	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
6 hour	□ Done □ Not Done	/ / :	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
12 hour	□ Done □ Not Done	/ / :	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
24 hour	□ Done □ Not Done	/ / :	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
48 hour	□ Done □ Not Done	/ / :	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
72 hour	□ Done □ Not Done	/ / :	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.

Form 14: PROPPR Research Blood Sample TEG and Multiplate Results *(cont.)*

Section C: TEG/Multiplate Wave Form/Raw Data

Sample Time Point	Wave Form / Raw Data Available?	
1st Available (Time Zero)	☐ **YES** →	Date information sent to HDCC/CORE LAB: __ __ / __ __ __ / __ __
	☐ **NO** →	□ Blood Sample Not Collected □ Other: _____
2 hour	☐ **YES** →	Date information sent to HDCC/CORE LAB: __ __ / __ __ __ / __ __
	☐ **NO** →	□ Blood Sample Not Collected □ Other: _____
4 hour	☐ **YES** →	Date information sent to HDCC/CORE LAB: __ __ / __ __ __ / __ __
	☐ **NO** →	□ Blood Sample Not Collected □ Other: _____
6 hour	☐ **YES** →	Date information sent to HDCC/CORE LAB: __ __ / __ __ __ / __ __
	☐ **NO** →	□ Blood Sample Not Collected □ Other: _____
12 hour	☐ **YES** →	Date information sent to HDCC/CORE LAB: __ __ / __ __ __ / __ __
	☐ **NO** →	□ Blood Sample Not Collected □ Other: _____
24 hour	☐ **YES** →	Date information sent to HDCC/CORE LAB: __ __ / __ __ __ / __ __
	☐ **NO** →	□ Blood Sample Not Collected □ Other: _____
48 hour	☐ **YES** →	Date information sent to HDCC/CORE LAB: __ __ / __ __ __ / __ __
	☐ **NO** →	□ Blood Sample Not Collected □ Other: _____
72 hour	☐ **YES** →	Date information sent to HDCC/CORE LAB: __ __ / __ __ __ / __ __
	☐ **NO** →	□ Blood Sample Not Collected □ Other: _____

Form 15: Anesthesia Data Sheet

Check here ☐ if there were no OR/IR visits during the initial resuscitation.

*(Complete this form only for the **initial OR/IR visit** during the resuscitation period. This form should be completed by the Anesthesiologist.)*

1. Date of Visit: __ __ / __ __ __ / __ __
   (dd/mmm/yy format)

2. Arrival Time: ___ : ___
   (24hr Clock in hh:mm)

3. Subject Location: ☐ OR ☐ IR

4. Was the subject intubated before arrival in OR/IR? ☐ Yes ☐ No

5. Record the total dose of pre-operative medications administered before arrival in OR/IR.

   Check here ☐if no pre-operative medications were administered. **Check here** ☐if pre-operative medications are unknown.

Hypnotics	Total Dose	Analgesics	Total Dose	Benzodiazepines	Total Dose	NMB Agents	Total Dose
Etomidate	mg	Morphine	mg	Midazolam	mg	Succinylcholine	mg
Propofol	mg	Hydromorphone	mg	Lorazepam	mg	Vecuronium	mg
Ketamine	mg	Fentanyl	mcg			Rocuronium	mg

6. Record the total dose of medications administered for induction & intubation in the OR/IR.

   Check here ☐if medications are unknown.

Hypnotics	Total Dose	Analgesics	Total Dose	Benzodiazepines	Total Dose	NMB Agents	Total Dose
Etomidate	mg	Morphine	mg	Midazolam	mg	Succinylcholine	mg
Propofol	mg	Hydromorphone	mg	Lorazepam	mg	Vecuronium	mg
Ketamine	mg	Fentanyl	mcg			Rocuronium	mg

7. Record the total dose of I.V. medications administered during the OR/IR procedure.

Hypnotics	Total Dose	Analgesics	Total Dose	Amnestics	Total Dose	NMB Agents	Total Dose
Etomidate	mg	Morphine	mg	Midazolam	mg	Succinylcholine	mg
Propofol	mg	Hydromorphone	mg	Lorazepam	mg	Vecuronium	mg
Ketamine	mg	Fentanyl	mcg	Scopolamine	mg	Rocuronium	mg

Form 15: Anesthesia Data Sheet *(cont.)*

8. Record the maximum dose in % for the following inhalation anesthetics administered during the OR/IR procedure.

Sevoflurane	%	Desflurane	%	Isoflurane	%

9. Record the following data at incision.

Blood Pressure *(mmHg)*		Pulse *(beats/min)*	SaO_2 %	ET CO_2
Systolic	Diastolic			
___ ___ ___	___ ___ ___	___ ___ ___		

10. Record the total dose of vasopressors, inotropes, and chronotropes administered during the procedure.

Ephedrine	mg	Phenylephrine	mcg	Epinephrine	mg	Norepinephrine	mg	Atropine	mg

11. Was mechanical ventilation used? ☐ Yes *(proceed to next question)* ☐ No *(skip to question #13)*

12. Record the mechanical ventilation mode and initial settings.

Mode: ☐Volume Limited ☐Pressure Limited

Initial Settings: Tidal Volume _____ ml, Rate _____, FiO_2 _____, PEEP_____

13. Were ABG samples sent for analysis during the OR/IR visit?
☐ Yes *(proceed to next question)* ☐ No *(stop here)*

14. Record the LAST arterial blood gas results obtained during the procedure below.

***Indicate unit of measure, then enter value in the table below:**	
CO_2? ☐ mmol/L ☐ mg/L ☐ mEq/L ☐ Other *(Specify):*	**HCO_3?** ☐ mmol/L ☐ mg/L ☐ Other *(Specify):*

	Time *(hh:mm)*	FiO_2 %	pH	PaO_2 (mmHg)	$PaCO_2$ (mmHg)	*CO_2	*HCO_3	SaO_2 %	Base (mmol/L)	
LAST ABG	__ __ : __ __	____	____	____	____	____	____	____	____	☐ Deficit ☐ Excess

Form 16: 24 Hour to 30 Day Follow-Up Assessments

(*Complete daily while subject remains in the ICU/IMU & twice weekly thereafter until discharge or at Day 30 of hospitalization. Collect all data elements from the previous 24 hours. If a" highest" and "lowest" value is needed and only one value is available, enter the value in* ***both*** *data fields. Print a new form for each assessment.)*

Check here ☐ if the subject died within the 1st 24hr's and/or before reaching the ICU/IMU/Nursing unit and proceed to the next form.

1. Assessment Date: ___ ___ / ___ ___ ___ / ___ ___
(dd/mmm/yy)

2. Subject Location: ☐ ICU ☐ IMU *(Monitored Unit)* ☐ Nursing Unit

3. Vital Signs:

Systolic Blood Pressure *(mmHg)*	Highest Reading:	Lowest Reading:
Diastolic Blood Pressure *(mmHg)*	Highest Reading:	Lowest Reading:
Heart Rate *(bpm)*	Highest Reading:	Lowest Reading:
Respiratory Rate	Highest Reading:	Lowest Reading:
Temperature ☐ F. ☐ C.	Highest Reading:	Lowest Reading:
CVP *(mmHg)*	Highest Reading:	Lowest Reading:
Mean Arterial Pressure *(MAP) (mmHg)*	Highest Reading:	Lowest Reading:

4. GCS and APACHE Scores:

(Record APACHE score if available)

Glasgow Coma Scale *(Record individual assessment scores or the GCS total)*		*Highest Score*	*Lowest Score*
	Eye Movement:		
	Verbal:		
	Motor:		
	GCS Total:		

APACHE *(select Scoring System)*	*Highest Score*	*Lowest Score*
☐ APACHE II		
☐ APACHE III		
☐ APACHE IV		

5. Lab Assessments:

Arterial Blood Gases	pH	Highest Reading:	Lowest Reading:
	FiO_2 *(for intubated patients)*	Highest Reading:	Lowest Reading:
	PaO_2	Highest Reading:	Lowest Reading:
	PaO_2 / FiO_2 Ratio *Corresponding values from the same time point.* ****Mild hypoxia*** *is defined as a PaO_2 / FiO_2 ratio <300 but ≥200,* ****Moderate hypoxia*** *is defined as a PaO_2 / FiO2 ratio < 200 mmHg*	Highest Reading:	Lowest Reading:
	$PaCO_2$	Highest Reading:	Lowest Reading:
	CO_2 ☐ mmol/L ☐ mg/L ☐ mEq/L ☐ Other *(specify):*	Highest Reading:	Lowest Reading:
	SaO_2 %	Highest Reading:	Lowest Reading:
	HCO_3 ☐ mmol/L ☐ mg/L ☐ Other *(specify):*	Highest Reading:	Lowest Reading:
	Base *(mmol/L)* ☐ Deficit ☐ Excess	Highest Reading:	
	Base *(mmol/L)* ☐ Deficit ☐ Excess	Lowest Reading:	

Form 16: 24 Hour to 30 Day Follow-Up Assessments *(cont.)*

5. Lab Assessments: *(cont.)*

Coagulation	PT *(seconds)*	Highest Reading:	Lowest Reading:
	PTT *(seconds)*	Highest Reading:	Lowest Reading:
	INR *(seconds)*	Highest Reading:	Lowest Reading:
	Fibrinogen ☐ mg/dL ☐ g/L ☐ Other *(specify):*	Highest Reading:	Lowest Reading:

Blood Count	Hgb *(Select measure)* ☐ mmol/L ☐ g/dL ☐ g/L ☐ Other *(specify):*	Highest Reading:	Lowest Reading:
	Hematocrit *(Hct %)*	Highest Reading:	Lowest Reading:
	WBC Count *(Select measure)* ☐ x 10^3/µL ☐ x 10^9/L ☐ x 10^3/ mm^3 ☐ Other *(specify):*	Highest Reading:	Lowest Reading:
	Platelets *(Select measure)* ☐ x 10^3/µL ☐ x 10^9/L ☐ x 10^3/ml^3 ☐ Other *(specify):*	Highest Reading:	Lowest Reading:

Chemistry & Metabolic Values	Sodium *(mEq/L)*	Highest Reading:	Lowest Reading:
	Potassium *(mEq/L)*	Highest Reading:	Lowest Reading:
	Chloride *(mEq/L)*	Highest Reading:	Lowest Reading:
	BUN *(mg/dL)*	Highest Reading:	Lowest Reading:
	Creatinine *(Select measure)* ☐ mg/dL ☐ µmol/L ☐ Other *(specify):*	Highest Reading:	Lowest Reading:
	Albumin *(Select measure)* ☐ g/L ☐ g/dL ☐ U/L ☐ µmol/L ☐ Other *(specify):*	Highest Reading:	Lowest Reading:
	Glucose *(Select measure)* ☐ mg/dL ☐ mmol/L ☐ Other *(specify):*	Highest Reading:	Lowest Reading:
	Lactate *(Select measure)* ☐mg/dL ☐mEq/L ☐mmol/L ☐ Other *(specify):*	Highest Reading:	Lowest Reading:
	Total Bilirubin *(Select measure)* ☐ mg/dL ☐ µmol/L ☐ Other *(specify):*	Highest Reading:	Lowest Reading:
	Calcium *(mg/dL)*	Highest Reading:	Lowest Reading:

6. Was the subject thought to have any of the following?

Acute Lung Injury *(ALI)*?	☐ Yes, *(Document on AE/SAE form 18)* ☐ No
Acute Respiratory Distress Syndrome *(ARDS)*?	☐ Yes, *(Document on AE/SAE form 18)* ☐ No
Pulmonary edema/respiratory failure from cardiac origin?	☐ Yes ☐ No
Pulmonary Contusions?	☐ Yes ☐ No
If intubated and displaying mild or moderate hypoxia *, does today's CXR/CT demonstrate bilateral infiltrates?	☐ Yes ☐ No ☐ NA

7. Did the subject require any of the following?

Mechanically Ventilated?	☐ Yes ↓ ☐ No ***(Enter ventilator settings below associated with the LOW PaO_2 / FiO_2 Ratio recorded above)***
Mode: ☐ Volume Limited ☐ Pressure Limited Tidal Volume: ml Rate: FiO_2: PIP: PEEP:	
Chemical Paralysis?	☐ Yes ☐ No
Vasopressors?	☐ Yes ☐ No
Dialysis?	☐ Yes ☐ No

8. Urine Output for the last 24 hours: ___ ___ ___ ___ *(ml.s)*

Form 17: Discharge/Death *(Initial Hospitalization through Day 30 of the PROPPR Protocol)*

1. Total (cumulative) number of ICU days: ___ ___

2. Total (cumulative) number of ventilator days: ___ ___

3. Insurance status on admission: *(Select one)*

□ Self Pay/None □ Private Insurance □ Medicare/Medicaid
□ Not Noted/Unknown □ Military Provider □ NA *(Canada Site Only)*

4. Insurance status at discharge, death, or Day 30 of protocol if still hospitalized: *(Select one)*

□ Self Pay/None □ Private Insurance □ Medicare/Medicaid
□ Not Noted/Unknown □ Military Provider □ NA *(Canada Site Only)*

5. Was there a reported history of anti-coagulant use prior to the injury?

□ Yes ↓ □ No □ Not Noted/Unknown

□ Warfarin □ Plavix □ Aspirin □ Thrombin Inhibitors □ Other, specify: _____

6. ***Prior to trauma***, was there a reported history of any of the following? *(Check all that apply)*

□ Alcohol Use
□ Acquired Immune Deficiency Syndrome *(AIDS)*
□ Cardiovascular Disease
□ Cirrhosis
□ COPD
□ Diabetes
□ Hepatic Failure
□ Hypertension
□ Immunosuppression
□ Leukemia/Multiple Myeloma
□ Lymphoma
□ Metastatic Cancer
□ Renal Disease
□ Tobacco Use *(smoking)*

7. Was a DNR ordered at any point during the hospitalization? □ Yes ↓ □ No
Time: ___:___ □ Unknown
(24hr Clock in hh:mm)
Dated: ___ / _____ / ___
(dd/mmm/yy)

8. Was care withdrawn at any point during the hospitalization? □ Yes ↓ □ No
Time: ___:___ □ Unknown
(24hr Clock in hh:mm)
Dated: ___ / _____ / ___
(dd/mmm/yy)

9. Did the subject die before day 30 of the initial hospitalization? □ Yes *(Go to question # 15)*
□ No *(Go to next question)*

10. Date of hospital discharge: ___ / _____ / ___ □ Remains Hospitalized on Day 30.
(dd/mmm/yy) *(Go to question #16)*

Form 17: Discharge/Death *(Initial Hospitalization through Day 30 of the PROPPR Protocol, cont.)*

11. Record the ***first*** 15 discharge diagnostic and procedure codes below.

Discharge Diagnostic Codes *(xxx.xx format)*		Procedure Codes *(xx.xx format)*	
(1) __ __ __ . __ __	(8) __ __ __ . __ __	(1) __ __ . __ __	(9) __ __ . __ __
(2) __ __ __ . __ __	(10) __ __ __ . __ __	(2) __ __ . __ __	(10) __ __ . __ __
(3) __ __ __ . __ __	(11) __ __ __ . __ __	(3) __ __ . __ __	(11) __ __ . __ __
(4) __ __ __ . __ __	(12) __ __ __ . __ __	(4) __ __ . __ __	(12) __ __ . __ __
(5) __ __ __ . __ __	(13) __ __ __ . __ __	(5) __ __ . __ __	(13) __ __ . __ __
(6) __ __ __ . __ __	(14) __ __ __ . __ __	(6) __ __ . __ __	(14) __ __ . __ __
(7) __ __ __ . __ __	(15) __ __ __ . __ __	(7) __ __ . __ __	(15) __ __ . __ __
(8) __ __ __ . __ __		(8) __ __ . __ __	

12. Did the subject leave AMA? □ Yes □ No

13. Subject discharged to?: *(Select one)*
- □ Home
- □ Long Term Care Facility
- □ Skilled Nursing Facility
- □ Rehabilitation Facility
- □ Hospice
- □ Acute Care Hospital
- □ Other, specify: _____

14. Was a Discharge Glasgow Coma Score (GCS) obtained?

□Yes ↓ □ No

GCS Score E: ___, V: ___, M: ___ or GCS Total Score if Component Scores Unknown: ___

GCS Scoring Key								
Eye Movement	1	No Response	Verbal	1	No Response / Intubated	Motor	1	No Response
	2	To Pain		2	Incomprehensible Sounds		2	Extension (Decerebrate)
	3	To Verbal Command		3	Inappropriate Words		3	Flexion – (Decorticate)
	4	Spontaneous		4	Disoriented, Converses		4	Flexion – Withdrawals From Pain
				5	Oriented, Converses		5	Localizes Pain
							6	Obeys Commands Appropriately

15. Was an extended Glasgow outcome scale (GOSE) obtained?

□ Yes, GOSE Score: _____ □ No

The Extended Glasgow Outcome Scale (GOSE) Scoring Key	
SCORE	Performance Level
1	Dead
2	Vegetative State
3	Lower severe disability; completely dependent on others
4	Upper severe disability; dependent on others for some activities
5	Lower moderate disability; unable to return to work or participate in social activities
6	Upper moderate disability; return to work at reduced capacity, reduced participation in social activity
7	Lower good recovery; good recovery with minor social or mental deficits
8	Upper good recovery

Form 17: Discharge/Death *(Initial Hospitalization through Day 30 of the PROPPR Protocol, cont.)*

16. Abbreviated Injury Scale (AIS) Score: **Check here** □ if the AIS Score was not noted/unknown.

ANATOMIC REGION	Head	Neck	Face	Chest	Abdomen	Extremity	External
INJURY# 1 Score							

17. Injury Severity Score (ISS): __ __ __ __ **Check here** □ if the ISS Score was not noted/unknown.

18. Date the 30 Day status information was confirmed *(Subject living or deceased)*: ____ /_____ /____
(dd/mmm/yy)

19. Source of Information: *(Select one)*
□ Medical Record □ Subject (self-report) □ Family/LAR
□ Other Healthcare Facility □ Vital Statistics/Death Registry
□ Other *(Specify)*: _____ □ Direct Observation

20. Subject status (primary outcome measure) 30 days after the initial hospital admission:

□ Deceased *(Go to next question)*
□ Living *(Stop here, this form is complete)*
□ Unknown/Lost to Follow-Up *(Stop here, this form is complete)*

21. Subject Location at time of death:

□ Home/Other Healthcare Facility □ ED □ OR □ IR □ ICU
□ Intermediate Level Care □ Nursing Unit □ Other *(Specify):* _____
□ Location Unknown/Information from Registry Database

22. Date of Death: ____/_____/____ □ Unknown *(Option available **only** for subjects who die **after** discharge)*
(dd/mmm/yy)

23. Time of Death: ___:___ □ Unknown *(Option available **only** for subjects who die **after** discharge)*
(24hr Clock in hh:mm)

24. Cause of Death: *(Check ALL that apply)*

□ Exsanguination / Hemorrhagic Shock
□ Traumatic Brain Injury (TBI)
□ Respiratory/Pulmonary Contusion/Tension Pneumothorax
□ Sepsis
□ Multiple Organ Failure (MOF)
□ Cardiovascular Event *(Select event(s) from below)*
○ Stroke ○ MI ○ Both Stroke & MI
□ Pulmonary Embolism
□ Transfusion Related Fatality
□ Other, *(Specify)*: _____
□ Unknown

PROPPR
Pragmatic, Randomized Optimal Platelet and Plasma Ratios

Study ID # ___ ___ ___ ___ ___ ___ ___

CONFIDENTIAL (Bar Code)

CRF Version Date: 2013 JUL 12 Completed By: ___ ___ ___

Form 18: Adverse Events & Serious Adverse Events (AEs, SAEs)

Check here ☐ if there are NO AE/SAE events to report.

*(Record any of the following complications that occurred during the subject's hospitalization. **** Hypertonic saline associated hypernatremia and transfusion associated graft vs. host disease should be reported to the HDCC within 3 days of discovery for FDA expedited reporting. Print additional pages as needed.)*

CODE	AE / SAE	CODE	AE / SAE	CODE	AE / SAE
1	Abdominal Compartment Syndrome (ACS)	13	Myocardial Infarction (MI)	25	Delayed Hemolytic Transfusion Reaction (DHTR)
2	Acute Kidney Injury	14	Abdominal Complication	26	Delayed Serological Transfusion Reaction (DSTR)
3	Acute Lung Injury	15	Other: (specify)	27	Febrile Non-Hemolytic Transfusion Reaction
4	Acute Respiratory Distress Syndrome (ARDS)	16	Pulmonary Embolism (PE), Symptomatic	28	Hypotensive Transfusion Reaction
5	Cardiac Arrest	17	Pulmonary Embolism (PE), Asymptomatic	29	Post Transfusion Purpura (PTP)
6	Death-NOT Transfusion Related	18	Re-Bleeding **After** Hemostasis Requiring I.R. / O.R. Procedure	30	Transfusion Associated Circulatory Overload (TACO)
7	Deep Vein Thrombosis (DVT)	19	Renal Failure	31	Transfusion Associated Dyspnea (TAD)
8	Drug Reaction	20	Sepsis	****32****	**Transfusion Associated Graft vs. Host Disease (TAGVHD)**
****9****	**Hypernatremia (associated with hypertonic saline)**	21	Stroke	33	Transfusion Related Acute Lung Injury (TRALI)
10	Infection (UTI, Wound, Line, etc.)	22	Systemic Inflammatory Response Syndrome (SIRS)	34	Transfusion Related Allergic Reactions
11	Mesenteric Thrombosis	23	Ventilator Associated Pneumonia (VAP)	35	Transfusion Related Metabolic Complication (Hypocalcemia/Hyperkalemia)
12	Multiple Organ Failure (MOF)	24	Acute Hemolytic Transfusion Reaction (AHTR)	36	Transfusion Transmitted Infection

↓

Code	AE / SAE	Start Date (dd/mmm/yy)	Stop Date (dd/mmm/yy)		Expected? (For Trauma Injuries)	Suspected? (Related to Randomized Blood Products)	Serious?
	☐ AE ☐ SAE	/ /	/ /	☐ Ongoing ☐Not Noted/Unknown	☐ Yes ☐ No	☐ Yes ☐ No	☐ 1 Non-Serious ☐ 2 Serious ☐ 3 Death
	☐ AE ☐ SAE	/ /	/ /	☐ Ongoing ☐Not Noted/Unknown	☐ Yes ☐ No	☐ Yes ☐ No	☐ 1 Non-Serious ☐ 2 Serious ☐ 3 Death
	☐ AE ☐ SAE	/ /	/ /	☐ Ongoing ☐Not Noted/Unknown	☐ Yes ☐ No	☐ Yes ☐ No	☐ 1 Non-Serious ☐ 2 Serious ☐ 3 Death
	☐ AE ☐ SAE	/ /	/ /	☐ Ongoing ☐Not Noted/Unknown	☐ Yes ☐ No	☐ Yes ☐ No	☐ 1 Non-Serious ☐ 2 Serious ☐ 3 Death
	☐ AE ☐ SAE	/ /	/ /	☐ Ongoing ☐Not Noted/Unknown	☐ Yes ☐ No	☐ Yes ☐ No	☐ 1 Non-Serious ☐ 2 Serious ☐ 3 Death
	☐ AE ☐ SAE	/ /	/ /	☐ Ongoing ☐Not Noted/Unknown	☐ Yes ☐ No	☐ Yes ☐ No	☐ 1 Non-Serious ☐ 2 Serious ☐ 3 Death
	☐ AE ☐ SAE	/ /	/ /	☐ Ongoing ☐Not Noted/Unknown	☐ Yes ☐ No	☐ Yes ☐ No	☐ 1 Non-Serious ☐ 2 Serious ☐ 3 Death

Refer to "Definitions of Complications Reported in PROPPR" reference for more information.

Site P.I. Name: Signature:

PROPPR
Pragmatic, Randomized Optimal Platelet and Plasma Ratios

Study ID # ___ ___ ___ ___ ___ ___ ___

CONFIDENTIAL **(Bar Code)**

CRF Version Date: 2013 JUL 12 Completed By: ___ ___ ___

Form 19: Subject / LAR Contact *(Document attempts to contact LAR for consent OR Subject/LAR for 30 day follow-up status here.)*

Check here ☐ if subject died before contact with LAR could be attempted.

Date *(dd/mmm/yy)*	Time *(hh:mm)*	Purpose	Type of Contact	Result
/ /	:	☐ Contacting LAR for Consent ☐ Contacting Subject/ LAR for 30 Day Status	☐ Phone ☐ Clinic Visit ☐ Letter/Certified Letter ☐ In Person ☐ e-mail ☐ Other: __________	☐ Made Contact, Consent Given ☐ Made Contact, Consent Not Given ☐ No Reply, Did Not Make Contact ☐ Note Additional Information on Form #22
/ /	:	☐ Contacting LAR for Consent ☐ Contacting Subject/ LAR for 30 Day Status	☐ Phone ☐ Clinic Visit ☐ Letter/Certified Letter ☐ In Person ☐ e-mail ☐ Other: __________	☐ Made Contact, Consent Given ☐ Made Contact, Consent Not Given ☐ No Reply, Did Not Make Contact ☐ Note Additional Information on Form #22
/ /	:	☐ Contacting LAR for Consent ☐ Contacting Subject/ LAR for 30 Day Status	☐ Phone ☐ Clinic Visit ☐ Letter/Certified Letter ☐ In Person ☐ e-mail ☐ Other: __________	☐ Made Contact, Consent Given ☐ Made Contact, Consent Not Given ☐ No Reply, Did Not Make Contact ☐ Note Additional Information on Form #22
/ /	:	☐ Contacting LAR for Consent ☐ Contacting Subject/ LAR for 30 Day Status	☐ Phone ☐ Clinic Visit ☐ Letter/Certified Letter ☐ In Person ☐ e-mail ☐ Other: __________	☐ Made Contact, Consent Given ☐ Made Contact, Consent Not Given ☐ No Reply, Did Not Make Contact ☐ Note Additional Information on Form #22
/ /	:	☐ Contacting LAR for Consent ☐ Contacting Subject/ LAR for 30 Day Status	☐ Phone ☐ Clinic Visit ☐ Letter/Certified Letter ☐ In Person ☐ e-mail ☐ Other: __________	☐ Made Contact, Consent Given ☐ Made Contact, Consent Not Given ☐ No Reply, Did Not Make Contact ☐ Note Additional Information on Form #22
/ /	:	☐ Contacting LAR for Consent ☐ Contacting Subject/ LAR for 30 Day Status	☐ Phone ☐ Clinic Visit ☐ Letter/Certified Letter ☐ In Person ☐ e-mail ☐ Other: __________	☐ Made Contact, Consent Given ☐ Made Contact, Consent Not Given ☐ No Reply, Did Not Make Contact ☐ Note Additional Information on Form #22

(Print additional pages if needed)

Form 20: Subject / LAR Consent

Check here ☐ if subject died before contact with LAR could be attempted.

1. Was the subjects' LAR notified of their participation?

☐ Yes *(Check all that apply)*
- □ Subject Date: ___/____/___ Time: ___ : ___
- □ LAR Date: ___/____/___ Time: ___ : ___

☐ No

2. Was consent obtained for study participation?

☐ Yes *(Check all that apply)*
- □ Subject Date: ___/____/___ Time: ___ : ___
- □ LAR Date: ___/____/___ Time: ___ : ___

☐ No

3. Was consent obtained for a follow-up call for Day-30 status?

☐ Yes *(Check all that apply)*
- □ Subject Date: ___/____/___ Time: ___ : ___
- □ LAR Date: ___/____/___ Time: ___ : ___

☐ No

☐ Not Applicable

4. Was HIPAA consent obtained to collect Day-30 status (if discharged to another care facility)?

☐ Yes *(Check all that apply)*
- □ Subject Date: ___/____/___ Time: ___ : ___
- □ LAR Date: ___/____/___ Time: ___ : ___

☐ No

☐ Not Applicable

Form 21: End of Study *(Complete this form for all randomized subjects.)*

Were any of the following criteria met?	**Yes**	**No**	**Date** *(dd/mmm/yy)*	**Time** *(24hr Clock in hh:mm)*
The subject withdrew consent.	☐	☐	/ /	:
The subjects' legally authorized representative withdrew consent.	☐	☐	/ /	:
The subject was detained or incarcerated before the study was completed.	☐	☐	/ /	:

Form 22: Additional Information

Check here ☐ if there are no additional comments.

Form #	Question #	Comments

(Print additional pages if needed)

Form 23: Trauma Registry Data Form *(Complete this form for all screening failures.)*

1. Was subject data entered into the trauma registry? ☐ Yes ☐ No

Form 24: Lab Sample Consent & Contact Record for Patients Screened but NOT randomized in PROPPR

1. What IRB approved method was used to obtain consent for use of the first available research blood sample? *(Select one)*
   - □ Modified Informed consent for 1 research blood sample and registry data collection. *(Continue to next question)*
   - □ Not applicable, local site IRB waiver of informed consent. *(Stop here)*

2. Document contact attempts below. **Check here** ☐ if the patient died before contact with LAR could be attempted.

Date *(dd/mmm/yy)*	**Time** *(24hr Clock in hh:mm)*	**Contact Source**	**Type of Contact**	**Result**
/ /	:	□ Patient □ LAR	□ Phone □ Clinic Visit □ Letter/Certified Letter □ In Person □ e-mail □ Other: ___________	□ Made Contact □ No Reply, Did Not Make Contact □ Note Additional Information on Form #22
/ /	:	□ Patient □ LAR	□ Phone □ Clinic Visit □ Letter/Certified Letter □ In Person □ e-mail □ Other: ___________	□ Made Contact □ No Reply, Did Not Make Contact □ Note Additional Information on Form #22
/ /	:	□ Patient □ LAR	□ Phone □ Clinic Visit □ Letter/Certified Letter □ In Person □ e-mail □ Other: ___________	□ Made Contact □ No Reply, Did Not Make Contact □ Note Additional Information on Form #22
/ /	:	□ Patient □ LAR	□ Phone □ Clinic Visit □ Letter/Certified Letter □ In Person □ e-mail □ Other: ___________	□ Made Contact □ No Reply, Did Not Make Contact □ Note Additional Information on Form #22
/ /	:	□ Patient □ LAR	□ Phone □ Clinic Visit □ Letter/Certified Letter □ In Person □ e-mail □ Other: ___________	□ Made Contact □ No Reply, Did Not Make Contact □ Note Additional Information on Form #22
/ /	:	□ Patient □ LAR	□ Phone □ Clinic Visit □ Letter/Certified Letter □ In Person □ e-mail □ Other: ___________	□ Made Contact □ No Reply, Did Not Make Contact □ Note Additional Information on Form #22

3. Was informed consent obtained?
   - □ Yes *(Continue to next question)* □ No *(Go to question #5)*

4. What option below did the Patient/LAR Select for use of the blood sample? *(Select one)*
   - □ Blood sample and other information may be kept and used in research to learn about and treat trauma injuries.
   - □ Blood sample and other information may be kept and used in research to learn about and treat trauma injuries or other health problems.
   - □ Blood sample and other information may not be used in future studies.
   - □ No restrictions on use of the blood sample were given.

5. If consent for the first available lab sample was NOT obtained, was the lab sampled destroyed?
   - □ Yes □ No