Study ID #: _____

PROPOLIS Medical Record Data Abstraction Form: Admission

Instructions: For all potentially eligible patients (including those who do not consent) please complete Sections 1 and 2 and then determine eligilibilty by filling out Section 3 using the information from Sections 1 and 2. Once a patient is determined eligible and has consented into the study, randomize them into either Plasma or Control group in REDCap (instructions for randomization can be found in the PROPOLIS Training Center (https://www.nattrauma.org/propolis-training-resources/). If any information is unknown, mark unknown rather than leaving blank.

Note: *If a participant dies after consenting into the study but before Hour 48*, fill out information up to the hour of death as completely as possible and then **fill out Section 3: Morbidity Assessment on the Hour 48 Form on page 18**.

Name of staff member screening and extracting medical record data: _____

Screening date (mm/dd/yyyy): _____

Screening time (24 hour clock): _____

Section 1: Demographics		
Date of admission to BICU *(mm/dd/yyyy)*:	**Date of birth *(mm/dd/yyyy)*:**	
Time of admission to BICU (24-hour clock):	**Age at time of admission (in years):**	
Sex: ☐ Male ☐ Female ☐ Unknown		
Section 2: Injury Information		
Date of burn: *(mm/dd/yyyy)*:	**Time of burn (24-hour clock):**	
Burn size, total (TBSA) (%):	**Burn size, full thickness (%):**	**Burn size, partial thickness (%):**
Burn etiology: ☐ 1-Scald ☐ 2-Flame ☐ 3-Contact	☐ 4-Electrical ☐ 5-Flash ☐ 6-Radiant/Laser/Cold	☐ 7-Other (if other, indicate etiology here): _____ ☐ 99-Unknown
Non-thermal injuries:	**Inhalation injury:** ☐ Yes ☐ No ☐ Unknown	

Section 3: Inclusion and Exclusion Criteria

Inclusion Criteria: Each box *must* be checked for the patient to be eligible for PROPOLIS

☐ Age >=18 years & <65 ☐ Weight > 40 kg (88.2 lbs)	☐ Initial assessment of thermal injury size >=20% TBSA ☐ Admitted to the burn center and enrollable within 8 hours of injury	☐ Expected to receive intravenous resuscitation fluids for at least 24 hours after injury ☐ Expected to live >24 hours after injury

Exclusion Criteria: Review the following criteria and *do not enroll the patient if any apply*. None of the boxes can be checked in order for the patient to be eligible to participate in PROPOLIS.

☐Chemical Injury ☐ Deep electric injury[1] ☐ Associated non-thermal injuries[2] ☐ Decision not to treat due to injury severity or other factors ☐ Patient already receiving plasma infusion or judged to be likely to require plasma infusion ☐ Patient already receiving "rescue procedures"[3]	☐ Age ≥65 years or <18 years ☐ Presence of anoxic brain injury that is not expected to result in complete recovery ☐ Inability to obtain informed consent	☐ Existence of any of the following pre-morbid conditions: 1. Congestive heart failure (NYHA Class IV)[4] 2. End-stage kidney disease (dialysis patient) 3. Cirrhosis of the liver 4. Oxygen-dependent chronic obstructive pulmonary disease 5. Malignancy: currently under treatment (e.g. chemotherapy, radiotherapy); or metastatic and assessed as untreatable 6. Previous bilateral lower extremity amputations

[1]Deep electric injury: high voltage electric injury causing gross myoglobinuria (clinical diagnosis)

[2]Associated non-thermal injuries: defined as a requirement (because of traumatic injury) for blood transfusion, major intracavitary surgery (craniotomy, thoracotomy, laparotomy), angioembolization, or endovascular surgery during the first 24 hours after injury

[3]Patient already receiving "rescue procedures": defined as albumin infusion, CRRT, TPE, or high-dose ascorbic acid

Eligibility determination:

☐ Yes, eligible (Proceed to consenting procedures. If the patient consents, randomize them in REDCap. If they do not consent, enter Sections 1, 2 and 3 into REDCap and then no further action needed)

☐ No, not eligible (no further action needed)

Section 4: Consent		
Was patient or LAR approached for consent? ☐ Yes ☐ No	**<u>If no</u>, why not?** ☐ LAR not available ☐ Missed patient/not able to approach in time ☐ Language barriers ☐ Family dynamics ☐ Other	**If other, please specify:**
Intent to consent indicated (or consent obtained) from patient or LAR? ☐ Yes ☐ No	**<u>If no,</u> choose the most important reason why patient or LAR did not consent:** ☐ Too overwhelmed with injury ☐ Not interested ☐ Did not respond (approached for consent but timed out) ☐ Other	**If other, please specify:**
Who is/will be providing consent? ☐ Patient ☐ Legally authorized representative	**Consent date (mm/dd/yyyy)**	**Consent time (24-hour clock)**
Is eConsent needed? ☐ Yes (send eConsent links via REDCap to patient or LAR) ☐ No (use paper consent forms)		
Randomization group (once a patient has consented to participate, fill in this information based on randomization assignment in REDCap): ☐ Control resuscitation ☐ Plasma resuscitation		

Admission Data Instructions: Complete Sections 5-7 for all *enrolled* participants at time of admission to burn center or as close as possible to admission.

Section 5: Admission Information	
Past medical history:	**Current medications:**
Height (cm):	**Weight (kg):**

Section 6: Admission Lab: Blood Sample		
Sodium (mEq/L):	**Potassium (mEq/L):**	**Chloride (mEq/L):**
Blood urea nitrogen (mg/dL):	**Creatinine (mg/dL):**	**Glucose (mg/dL):**
Magnesium (mg/dL):	**Ionized calcium (mg/dL):**	**Phosphate (mg/dL):**
Total bilirubin (mg/dL) (if available):	**Albumin (g/dL):**	**AST (units/L) (if available):**
ALT (IU/L) (if available):	**ALP (IU/L) (if available):**	**Hemoglobin (mg/dL):**
Hematocrit (%):	**White blood cells (x 10^3/mm^3):**	**Platelet count (×103/µL):**
Prothrombin time (seconds):	**Partial prothrombin time (seconds):**	**INR:**

Section 7: Pre-BICU Intake and Output	
Pre BICU total fluids infused (Includes prehospital and ED): **Specify type of fluids:**	**Pre-BICU total output:**

Study ID #: _____

PROPOLIS Medical Record Data Abstraction Form: Ventilator Data: Admission-Hour 48

Instructions: Record initial ventilator data at admission and hours 6, 12, 18, 24, 36, and 48 within +-1 hour. The admission timepoint is defined as the first time each item was measured after admission to burn center and is needed (regardless of post burn hours (PBH). See the Hourly Data Collection spreadsheet for assistance with determining time for data collection.
Note: Ventilator data date and time should match arterial blood gas date and time.

Ventilator Mode key							
1	VC	3	PRVC	5	PS	7	VDR
2	PC	4	SIMV	6	APRV	8	Other

Hour Interval	**Date** *(mm/dd /yyyy)*	**Time** *(hh:mm)*	**In OR during this PBH? (yes/no)**	**Fraction of inspired oxygen (%)**	**Ventilator Mode**	**Respiratory Rate (set)? y/n**	**Tidal volume (ml)**	**Mean Airway Pressure**	**Positive End Expiratory Pressure (PEEP)**	**Plateau Pressure**	**Peak Pressure**
Admission	/ /	:				☐ Yes ☐ No					
6 hours PBH	/ /	:				☐ Yes ☐ No					
12 hours PBH	/ /	:				☐ Yes ☐ No					
18 hours PBH	/ /	:				☐ Yes ☐ No					
24 hours PBH	/ /	:				☐ Yes ☐ No					
36 hours PBH	/ /	:				☐ Yes ☐ No					
48 hours PBH	/ /	:				☐ Yes ☐ No					

Study ID #: _____

PROPOLIS Medical Record Data Abstraction Form: Vital Signs & Glasgow Coma Scale: Admission-Hour 48

Instructions: Record initial vital signs and GCS at admission and hours 6, 12, 18, 24, 36, and 48 within +-1 hour. The admission timepoint is defined as the first time each item was measured after admission to burn center and is needed (regardless of post burn hours (PBH). See the Hourly Data Collection spreadsheet for assistance with determining time for data collection.

Note: The GCS should be administered in the absence of sedation (ie, during a daily sedation break) if possible.

GCS Scoring Key

Eye Movement€		
	1	No Response
	2	To Pain
	3	To Verbal Command
	4	Spontaneous

Verbal (V)		
	1	No Response / Intubated
	2	Incomprehensible Sounds
	3	Inappropriate Words
	4	Disoriented, Converses
	5	Oriented, Converses

Motor(M)		
	1	No Response
	2	Extension *(Decerebrate)*
	3	Flexion – *(Decorticate)*
	4	Flexion – Withdrawals From Pain
	5	Localizes Pain
	6	Obeys Commands Appropriately

Hour Interval	Date *(mm/dd /yyyy)*	Time *(hh:mm)*	In OR during this PBH VS? (yes/no)	Blood Pressure *(mmHg)*		Mean Arterial Pressure	Heart Rate *(beats/min)*	Oxygen Saturation	Respiratory Rate	Temperature in Celsius	GCS
				Systolic	Diastolic						Record EVM Scores and GCS Total Score
Admission	/ /	:									E:____M: ____ V:____Total:____
6 hours PBH	/ /	:									E:____M: ____ V:____Total:____
12 hours PBH	/ /	:									E:____M: ____ V:____Total:____
18 hours PBH	/ /	:									E:____M: ____ V:____Total:____
24 hours PBH	/ /	:									E:____M: ____ V:____Total:____
36 hours PBH	/ /	:									E:____M: ____ V:____Total:____
48 hours PBH	/ /	:									E:____M: ____ V:____Total:____

Study ID #: _____

PROPOLIS Medical Record Data Abstraction Form: Arterial Blood Gas: Admission-Hour 48								
Instructions: Record initial arterial blood gas values at admission and hours 6, 12, 18, 24, 36, and 48 within +-1 hour. The admission timepoint is defined as the first time each item was measured after admission to burn center and is needed (regardless of post burn hours (PBH). See the Hourly Data Collection spreadsheet for assistance with determining time for data collection.								
Hour Interval	**Date** *(mm/dd /yyyy)*	**Time** *(hh:mm)*	**Arterial blood pH** (temp corrected)	**Arterial blood PaO2** (mmHg) (temp corrected)	**Arterial blood PaCO2** (mmHg) (temp corrected)	**Arterial blood base excess** (mmol/L)	**Arterial blood lactate** (mmol/L)	**Fraction of inspired oxygen, %:**
Admission	/ /	:						
6 hours PBH	/ /	:						
12 hours PBH	/ /	:						
18 hours PBH	/ /	:						
24 hours PBH	/ /	:						
36 hours PBH	/ /	:						
48 hours PBH	/ /	:						

Study ID #: _____

Intake/Output hourly up to 48 hours *(Note: this form is on the 48-Hour timepoint in REDCap for data entry)*															
PBH	**Date** *(mm/dd/yyyy)*	**Time** *(hh:mm)*	**In OR during this PBH I/O** (yes/no)	**Lactated ringers (ml)**	**Albumin 5% (ml)**	**Albumin 25% (ml)**	**Packed red blood cells (ml)**	**Other colloid (ml)**	**Other crystalloid (ml)**	**Pathogen reduced plasma (ml)**	**Other plasma (ml)**	**Enteral nutrition (ml)**	**Other fluids (ml)**	**Total fluids infused (ml)**	**Urine output (ml)**
1															
2															
3															
4															
5															
6															
7															
8															
9															
10															
11															
12															
13															
14															
15															
16															
17															
18															
19															

Study ID #: _____

PBH	Date *(mm/dd/yyyy)*	Time *(hh:mm)*	In OR during this PBH I/O (yes/no)	Lactated ringers (ml)	Albumin 5% (ml)	Albumin 25% (ml)	Packed red blood cells (ml)	Other colloid (ml)	Other crystalloid (ml)	Pathogen reduced plasma (ml)	Other plasma (ml)	Enteral nutrition (ml)	Other fluids (ml)	Total fluids infused (ml)	Urine output (ml)
20															
21															
22															
23															
24															
25															
26															
27															
28															
29															
30															
31															
32															
33															
34															
35															
36															
37															
38															
39															

Study ID #: _____

PBH	Date *(mm/dd/yyyy)*	Time *(hh:mm)*	In OR during this PBH I/O (yes/no)	Lactated ringers (ml)	Albumin 5% (ml)	Albumin 25% (ml)	Packed red blood cells (ml)	Other colloid (ml)	Other crystalloid (ml)	Pathogen reduced plasma (ml)	Other plasma (ml)	Enteral nutrition (ml)	Other fluids (ml)	Total fluids infused (ml)	Urine output (ml)
40															
41															
42															
43															
44															
45															
46															
47															
48															

PROPOLIS Medical Record Data Abstraction Form: Hour 12

Instructions: Fill out the CRF as completely as possible, indicated missing or unknown values rather than leaving them blank. Data collection window for Hour 12 is +/- 1 hour (i.e., data can be collected between hours 11 and 13).

Name of staff member screening and extracting medical record data: _____

Section 1: Laboratory Values from Blood Sample
Platelet count:

PROPOLIS Medical Record Data Abstraction Form: Hour 24

Instructions: Fill out the CRF as completely as possible, indicated missing or unknown values rather than leaving them blank. Data collection window for Hour 24 is +/- 1 hour (i.e., data can be collected between hours 23 and 25).

Name of staff member screening and extracting medical record data: _____

<table>
<tr><th colspan="2">Section 1: Laboratory Values from Blood Sample</th></tr>
<tr><td>Creatinine (mg/dL):</td><td>Platelet count:</td></tr>
<tr><th colspan="2">Section 2: SOFA Score: Admission Day
Instructions: Use admission GCS and assume normal Bilirubin
<u>Note</u>: The GCS should be administered in the absence of sedation (ie, during a daily sedation break) if possible.</th></tr>
<tr><td>PaO_2/FiO_2, mmHg:
☐ ≥400 (0)
☐ 300-399 (+1)
☐ 200-299 (+2)
☐ ≤199 and NOT mechanically ventilated (+2)
☐ 100-199 and mechanically ventilated (+3)
☐ <100 and mechanically ventilated (+4)</td><td>Platelets, $\times 10^3/\mu L$:
☐ ≥150 (0)
☐ 100-149 (+1)
☐ 50-99 (+2)
☐ 20-49 (+3)
☐ <20 (+4)</td></tr>
<tr><td>Glasgow Coma Scale Score (use GCS on admission here):
☐ 15 (0)
☐ 13-14 (+1)
☐ 10-12 (+2)
☐ 6-9 (+3)
☐ <6 (+4)</td><td>Bilirubin, mg/dL (µmol/L): (assume normal, or <1.2 (<20))
☒ <1.2 (<20) (0)
☐ 1.2–1.9 (20-32) (+1)
☐ 2.0–5.9 (33-101) (+2)
☐ 6.0–11.9 (102-204) (+3)
☐ ≥12.0 (>204) (+4)</td></tr>
<tr><td rowspan="2">Mean arterial pressure OR administration of vasoactive agents required (listed doses are in units of mcg/kg/min):
☐ No hypotension (0)
☐ MAP <70 mmHg (+1)
☐ Dopamine ≤5 or dobutamine (any dose) (+2)
☐ Dopamine >5, epinephrine ≤0.1, or norepinephrine ≤0.1 (+3)
☐ Dopamine >15, epinephrine >0.1, or norepinephrine >0.1 (+4)</td><td>Creatinine, mg/dL (or urine output):
☐ <1.2 (0)
☐ 1.2–1.9 (+1)
☐ 2.0–3.4 (+2)
☐ 3.5–4.9 or UOP <500 mL/day) (+3)
☐ ≥5.0 or UOP <200 mL/day (+4)</td></tr>
<tr><td>Add the selected values for the total SOFA Score (max score is 24):</td></tr>
</table>

Section 3: Norepinephrine equivalents:[6]		
Norepinephrine (equivalent dose=1) ☐ Yes ☐ No ☐ Unknown **Dose (mcg/min):**	**Epinephrine (equivalent dose=1)** ☐ Yes ☐ No ☐ Unknown **Dose (mcg/min):**	**Dopamine (E1,E2) (equivalent dose=0.01)** ☐ Yes ☐ No ☐ Unknown **Dose (mcg/kg/min):**
Vasopressin (E3) (equivalent dose=5*) ☐ Yes ☐ No ☐ Unknown *approx. conversion noted in units/min to equivalent norepinephrine dose in mcg/kg/min **Dose (units/min):**	**Phenylephrine (E4) (equivalent dose=0.45)** ☐ Yes ☐ No ☐ Unknown **Dose (mcg/min):**	

PROPOLIS Medical Record Data Abstraction Form: Hour 48

Instructions: Fill out the CRF as completely as possible, indicated missing or unknown values rather than leaving them blank. Data collection window for Hour 48 is +/- 1 hour (i.e., data can be collected between hours 47 and 49).

Name of staff member screening and extracting medical record data: _____

Section 1: Laboratory Values from Blood Sample

Creatinine (mg/dL):	**Platelet count:**

Section 2: 48-Hour Resuscitation Morbidity Assessment *(i.e., did these instances occur by hour 48?)*

Death:	**Compartment syndrome (abdominal, extremity, or orbital)**	**Compartment syndrome decompression (check all that apply):**
☐ Yes ☐ No	☐ Yes ☐ No ☐ Unknown **If yes, which? (select all that apply)** ☐ Orbital ☐ Abdominal ☐ Extremity **Describe diagnosis method (e.g., orbital (OCS) manifested by intraocular pressure of 35 mmHg):**	☐ None ☐ OCS treated with canthotomy/cantholysis ☐ ACS treated with paracentesis or laparotomy ☐ ECS treated with fasciotomy ☐ Other ☐ Unknown

Cardiac arrest:	**Myocardial infarction:**
☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown
Stroke:	**Bowel infarction:**
☐ Yes ☐ No ☐ Unknown	☐ Yes ☐ No ☐ Unknown

KDIGO Grading of Acute Kidney Injury (AKI)

Instructions: Diagnosis of AKI requires meeting one of the following 3 criteria:

Criterion 1: Increase in creatinine of 1.5 x baseline

Instructions: Most often in this study the baseline creatinine will be the creatinine on admission, and an increase of 1.5 x over this baseline (over a 7-day period) is defined as AKI. But: (a) If the patient had a known lower creatinine within the last 6-12 months, then this lower value could be used as the baseline. (b) If with resuscitation the patient's creatinine improves from admission to a new, lower value, then this improved value could be used as the true baseline.

What was the baseline serum creatinine (Cr-baseline)? (mg/dl) (use value collected in Admission Section 6 OR known value within last 6-12 months)	What is the current serum creatinine (Cr-current)? (mg/dl) (use value collected in Hour 48 Section 1)

Is Cr-current > Cr-baseline? ☐ No ☐ Yes	**If yes**, calculate: Cr-current/Cr-baseline= _____(times)

Criterion 2: Increase in creatinine of 0.3 mg/dl over the last 48 hrs

Instructions: The criterion of a 0.3-mg/dL increase is strictly defined as the difference between 2 measurements obtained within a 48-hour period. No presumption of a pre-existing baseline level may be made.

What was the serum creatinine 48 hrs ago ($Cr_{forty\text{-}eight\ hrs}$)? (Use value collected in Admission Section 6) _____mg/dl	What is the current serum creatinine ($Cr_{current}$)? (use value collected in Hour 48 Section 1) _____ mg/dl	Calculate: $Cr_{current}$ - $Cr_{forty\text{-}eight\ hrs}$ = _____ mg/dl

Criterion 3: Decrease in urine output

What is the patient's current weight? (kg)	What was the average urine output over the last:
	6 hours? (ml/kg/h)
	12 hours? (ml/kg/h)
	24 hours? (ml/kg/h)

Kidney Injury Stage (*circle correct value*):

Stage	Serum Creatinine	Urine output
0	Does not meet any of criteria noted below	Does not meet any of criteria noted below
1	1.5-1.9 times baseline OR >0.3 mg/dl increase over 48 hours	<0.5 ml/kg/h for 6-12 hours
2	2.0-2.9 times baseline	<0.5 ml/kg/h for ≥ 12 hours
3	3.0 times baseline OR Increase in serum creatinine to > 4.0 mg/dl OR Initiation of renal replacement therapy	<0.3 ml/kg/h for ≥ 24 hours OR Anuria for ≥ 12 hours

Section 3: 48-Hour Assessment *Instructions: For all hours, round to nearest hour*	
Continuous Renal Replacement Therapy performed: ☐ Yes ☐ No ☐ Unknown	**Continuous Renal Replacement Therapy duration (hours):**
Therapeutic plasma exchange performed: ☐ Yes ☐ No ☐ Unknown	**Therapeutic plasma exchange duration (hours):**
High dose ascorbic acid infused: ☐ Yes ☐ No ☐ Unknown	**High dose ascorbic acid infusion duration (hours):**
Mechanical ventilation: ☐ Yes ☐ No ☐ Unknown	**Mechanical ventilation duration (hours):**

Section 4: SOFA Score: Day 2 *Instructions: For each data element, use worst values from last 24 hours.* *Note: The GCS should be administered in the absence of sedation (ie, during a daily sedation break) if possible.*	
PaO_2/FiO_2, mmHg: ☐ ≥400 (0) ☐ 300-399 (+1) ☐ 200-299 (+2) ☐ ≤199 and NOT mechanically ventilated (+2) ☐ 100-199 and mechanically ventilated (+3) ☐ <100 and mechanically ventilated (+4)	**Platelets, $\times 10^3/\mu L$:** ☐ ≥150 (0) ☐ 100-149 (+1) ☐ 50-99 (+2) ☐ 20-49 (+3) ☐ <20 (+4)
Glasgow Coma Scale Score: ☐ 15 (0) ☐ 13-14 (+1) ☐ 10-12 (+2) ☐ 6-9 (+3) ☐ <6 (+4)	**Bilirubin, mg/dL (µmol/L):** *(assume normal, or <1.2 (<20))* ☒<1.2 (<20) (0) ☐ 1.2–1.9 (20-32) (+1) ☐ 2.0–5.9 (33-101) (+2) ☐ 6.0–11.9 (102-204) (+3) ☐ ≥12.0 (>204) (+4)

Mean arterial pressure OR administration of vasoactive agents required (listed doses are in units of mcg/kg/min): ☐ No hypotension (0) ☐ MAP <70 mmHg (+1) ☐ Dopamine ≤5 or dobutamine (any dose) (+2) ☐ Dopamine >5, epinephrine ≤0.1, or norepinephrine ≤0.1 (+3) ☐ Dopamine >15, epinephrine >0.1, or norepinephrine >0.1 (+4)	**Creatinine, mg/dL (or urine output):** ☐ <1.2 (0) ☐ 1.2–1.9 (+1) ☐ 2.0–3.4 (+2) ☐ 3.5–4.9 or UOP <500 mL/day) (+3) ☐ ≥5.0 or UOP <200 mL/day (+4) **Add the selected values for the total SOFA Score (max score is 24):**

Section 5: Norepinephrine equivalents:[6]		
Norepinephrine (equivalent dose=1) ☐ Yes ☐ No ☐ Unknown **Dose (mcg/min):**	**Epinephrine (equivalent dose=1)** ☐ Yes ☐ No ☐ Unknown **Dose (mcg/min):**	**Dopamine (E1,E2) (equivalent dose=0.01)** ☐ Yes ☐ No ☐ Unknown **Dose (mcg/kg/min):**
Vasopressin (E3) (equivalent dose=5*) ☐ Yes ☐ No ☐ Unknown *approx. conversion noted in units/min to equivalent norepinephrine dose in mcg/kg/min **Dose (units/min):**	**Phenylephrine (E4) (equivalent dose=0.45)** ☐ Yes ☐ No ☐ Unknown **Dose (mcg/min):**	

PROPOLIS Medical Record Data Abstraction Form: Hour 72

Instructions: Fill out the CRF as completely as possible, indicated missing or unknown values rather than leaving them blank. Data collection window for Hour 72 is +/- 1 hour (i.e., data can be collected between hours 71 and 73).

Name of staff member screening and extracting medical record data: _____

Hour 72 Status:

☐ 1-In hospital

☐ 2-Already discharged *(Instructions: Don't fill in any 72 hour data except SOFA score if they were discharged on day 3. Ie, collect SOFA score on day of discharge)*

☐ 3-Dead *(Instructions: Don't fill in any 72 hour data except SOFA score if they died on day 3. Ie, collect SOFA score on day of death)*

Section 1: 72-Hour Assessment: Transfusion related acute lung injury (TRALI)	
Patient must meet **ONE** of the following criteria for a diagnosis of TRALI:	
Does <u>not</u> have an existing (pre-transfusion) diagnosis of ARDS: ☐ Yes ☐ No (<u>does</u> have existing diagnosis of ARDS) ☐ Unknown	**Does have an existing (pre-transfusion) diagnosis of ARDS in the <u>mild</u> range (PaO_2/FiO_2 200-300), which then deteriorated (PaO_2/FiO_2 < 200) after transfusion:** ☐ Yes ☐ No ☐ Unknown
In addition, patient must meet **ALL** of the following criteria:	
The respiratory status (e.g., PaO_2/FiO_2, level of respiratory support) was <u>stable</u> in the 12 hours pre-transfusion ☐ Yes ☐ No ☐ Unknown	**Deterioration in oxygenation is of <u>acute onset</u>, i.e., occurs within 6 hours of transfusion** ☐ Yes ☐ No ☐ Unknown
Hypoxemia (PaO_2/FiO_2 < 300 or, for patients meeting criterion 2, PaO_2/FiO_2 < 200) ☐ Yes ☐ No ☐ Unknown **PaO_2/FiO_2** = _____ mmHg	**Clear evidence of pulmonary edema on chest imaging (CXR, CT, or ultrasound** ☐ Yes ☐ No ☐ Unknown **Describe (if yes):**
No evidence of left atrial hypertension (if suspected, perform e.g. echocardiography) ☐ Yes ☐ No ☐ Unknown **Describe diagnostic procedures performed (if any):**	**Did the patient have TRALI (ie, they met one criteria in the first section, above, and all criteria in the second section)?** ☐ Yes ☐ No ☐ Unknown

Section 2: SOFA Score: Day 3

Instructions: For each data element, use worst values from last 24 hours.

Note: The GCS should be administered in the absence of sedation (ie, during a daily sedation break) if possible.

PaO_2/FiO_2, mmHg: ☐ ≥400 (0) ☐ 300-399 (+1) ☐ 200-299 (+2) ☐ ≤199 and NOT mechanically ventilated (+2) ☐ 100-199 and mechanically ventilated (+3) ☐ <100 and mechanically ventilated (+4)	**Platelets, $\times 10^3/\mu L$:** ☐ ≥150 (0) ☐ 100-149 (+1) ☐ 50-99 (+2) ☐ 20-49 (+3) ☐ <20 (+4)
Glasgow Coma Scale Score: ☐ 15 (0) ☐ 13-14 (+1) ☐ 10-12 (+2) ☐ 6-9 (+3) ☐ <6 (+4)	**Bilirubin, mg/dL (µmol/L):** *(assume normal, or <1.2 (<20))* ☒ <1.2 (<20) (0) ☐ 1.2–1.9 (20-32) (+1) ☐ 2.0–5.9 (33-101) (+2) ☐ 6.0–11.9 (102-204) (+3) ☐ ≥12.0 (>204) (+4)
Mean arterial pressure OR administration of vasoactive agents required (listed doses are in units of mcg/kg/min): ☐ No hypotension (0) ☐ MAP <70 mmHg (+1) ☐ Dopamine ≤5 or dobutamine (any dose) (+2) ☐ Dopamine >5, epinephrine ≤0.1, or norepinephrine ≤0.1 (+3) ☐ Dopamine >15, epinephrine >0.1, or norepinephrine >0.1 (+4)	**Creatinine, mg/dL (or urine output):** ☐ <1.2 (0) ☐ 1.2–1.9 (+1) ☐ 2.0–3.4 (+2) ☐ 3.5–4.9 or UOP <500 mL/day) (+3) ☐ ≥5.0 or UOP <200 mL/day (+4) **Add the selected values for the total SOFA Score (max score is 24):**

PROPOLIS Medical Record Data Abstraction Form: Days 4-6

Instructions: Indicate status of participant at each day. If the participant has been discharged or died before Day 4, 5, or 6, do not fill out any more information. If they died on Day 4, 5, or 6, fill out the SOFA score for that day.

Name of staff member screening and extracting medical record data: _____

Screening date (mm/dd/yyyy): _____

Section 1: SOFA Score: Day 4

Instructions: For each data element, use worst values from last 24 hours.

Note: The GCS should be administered in the absence of sedation (ie, during a daily sedation break) if possible.

Day 4 Status:

☐ In hospital

☐ Already discharged *(Instructions: Don't fill in any Day 4 data unless they were discharged ON Day 4, ie, collect SOFA on day of discharge)*

☐ Dead *(Instructions: Don't fill in any Day 4 data unless they died ON Day 4, ie, collect SOFA on day of death)*

PaO_2/FiO_2, mmHg:

☐ ≥400 (0)
☐ 300-399 (+1)
☐ 200-299 (+2)
☐ ≤199 and NOT mechanically ventilated (+2)
☐ 100-199 and mechanically ventilated (+3)
☐ <100 and mechanically ventilated (+4)

Platelets, $\times 10^3/\mu L$:

☐ ≥150 (0)
☐ 100-149 (+1)
☐ 50-99 (+2)
☐ 20-49 (+3)
☐ <20 (+4)

Glasgow Coma Scale Score:

☐ 15 (0)
☐ 13-14 (+1)
☐ 10-12 (+2)
☐ 6-9 (+3)
☐ <6 (+4)

Bilirubin, mg/dL (µmol/L): *(assume normal, or <1.2 (<20))*

☒ <1.2 (<20) (0)
☐ 1.2–1.9 (20-32) (+1)
☐ 2.0–5.9 (33-101) (+2)
☐ 6.0–11.9 (102-204) (+3)
☐ ≥12.0 (>204) (+4)

Mean arterial pressure OR administration of vasoactive agents required (listed doses are in units of mcg/kg/min):

☐ No hypotension (0)
☐ MAP <70 mmHg (+1)
☐ Dopamine ≤5 or dobutamine (any dose) (+2)
☐ Dopamine >5, epinephrine ≤0.1, or norepinephrine ≤0.1 (+3)
☐ Dopamine >15, epinephrine >0.1, or norepinephrine >0.1 (+4)

Creatinine, mg/dL (or urine output):

☐ <1.2 (0)
☐ 1.2–1.9 (+1)
☐ 2.0–3.4 (+2)
☐ 3.5–4.9 or UOP <500 mL/day) (+3)
☐ ≥5.0 or UOP <200 mL/day (+4)

Add the selected values for the total SOFA Score (max score is 24):

Section 2: SOFA Score: Day 5

Instructions: For each data element, use worst values from last 24 hours.

Note: The GCS should be administered in the absence of sedation (ie, during a daily sedation break) if possible.

Day 5 Status:

☐ In hospital

☐ Already discharged *(Instructions: Don't fill in any Day 5 data unless they were discharged ON Day 5, ie, collect SOFA on day of discharge)*

☐ Dead *(Instructions: Don't fill in any Day 5 data unless they died ON Day 5, ie, collect SOFA on day of death)*

PaO_2/FiO_2, mmHg:

☐ ≥400 (0)

☐ 300-399 (+1)

☐ 200-299 (+2)

☐ ≤199 and NOT mechanically ventilated (+2)

☐ 100-199 and mechanically ventilated (+3)

☐ <100 and mechanically ventilated (+4)

Platelets, $\times 10^3/\mu L$:

☐ ≥150 (0)

☐ 100-149 (+1)

☐ 50-99 (+2)

☐ 20-49 (+3)

☐ <20 (+4)

Glasgow Coma Scale Score:

☐ 15 (0)

☐ 13-14 (+1)

☐ 10-12 (+2)

☐ 6-9 (+3)

☐ <6 (+4)

Bilirubin, mg/dL (µmol/L): *(assume normal, or <1.2 (<20))*

☒ <1.2 (<20) (0)

☐ 1.2–1.9 (20-32) (+1)

☐ 2.0–5.9 (33-101) (+2)

☐ 6.0–11.9 (102-204) (+3)

☐ ≥12.0 (>204) (+4)

Mean arterial pressure OR administration of vasoactive agents required (listed doses are in units of mcg/kg/min):

☐ No hypotension (0)

☐ MAP <70 mmHg (+1)

☐ Dopamine ≤5 or dobutamine (any dose) (+2)

☐ Dopamine >5, epinephrine ≤0.1, or norepinephrine ≤0.1 (+3)

☐ Dopamine >15, epinephrine >0.1, or norepinephrine >0.1 (+4)

Creatinine, mg/dL (or urine output):

☐ <1.2 (0)

☐ 1.2–1.9 (+1)

☐ 2.0–3.4 (+2)

☐ 3.5–4.9 or UOP <500 mL/day) (+3)

☐ ≥5.0 or UOP <200 mL/day (+4)

Add the selected values for the total SOFA Score (max score is 24):

Section 3: SOFA Score: Day 6

Instructions: For each data element, use worst values from last 24 hours.

Note: The GCS should be administered in the absence of sedation (ie, during a daily sedation break) if possible.

Day 6 Status:

☐ In hospital

☐ Already discharged *(Instructions: Don't fill in any Day 6 data unless they were discharged ON Day 6, ie, collect SOFA on day of discharge)*

☐ Dead *(Instructions: Don't fill in any Day 6 data unless they died ON Day 6, ie, collect SOFA on day of death)*

PaO_2/FiO_2, mmHg:

☐ ≥400 (0)

☐ 300-399 (+1)

☐ 200-299 (+2)

☐ ≤199 and NOT mechanically ventilated (+2)

☐ 100-199 and mechanically ventilated (+3)

☐ <100 and mechanically ventilated (+4)

Platelets, $\times 10^3/\mu L$:

☐ ≥150 (0)

☐ 100-149 (+1)

☐ 50-99 (+2)

☐ 20-49 (+3)

☐ <20 (+4)

Glasgow Coma Scale Score:

☐ 15 (0)

☐ 13-14 (+1)

☐ 10-12 (+2)

☐ 6-9 (+3)

☐ <6 (+4)

Bilirubin, mg/dL (µmol/L): *(assume normal, or <1.2 (<20))*

☒ <1.2 (<20) (0)

☐ 1.2–1.9 (20-32) (+1)

☐ 2.0–5.9 (33-101) (+2)

☐ 6.0–11.9 (102-204) (+3)

☐ ≥12.0 (>204) (+4)

Mean arterial pressure OR administration of vasoactive agents required (listed doses are in units of mcg/kg/min):

☐ No hypotension (0)

☐ MAP <70 mmHg (+1)

☐ Dopamine ≤5 or dobutamine (any dose) (+2)

☐ Dopamine >5, epinephrine ≤0.1, or norepinephrine ≤0.1 (+3)

☐ Dopamine >15, epinephrine >0.1, or norepinephrine >0.1 (+4)

Creatinine, mg/dL (or urine output):

☐ <1.2 (0)

☐ 1.2–1.9 (+1)

☐ 2.0–3.4 (+2)

☐ 3.5–4.9 or UOP <500 mL/day) (+3)

☐ ≥5.0 or UOP <200 mL/day (+4)

Add the selected values for the total SOFA Score (max score is 24):

PROPOLIS Medical Record Data Abstraction Form: Day 7

Instructions: Fill out information as fully as possible, including for those participants who died or were discharged before Day 7, except where instructions indicate otherwise. DVT or ARDS should be collected for any days up to and including day 7, not just on day 7. Mark unknown rather than leaving any items blank.

Name of staff member screening and extracting medical record data: _____

Screening date (mm/dd/yyyy): _____

Day 7 Status:

☐ In hospital
☐ Already discharged
☐ Dead

Section 1: Day 7 Assessment

Thromboembolic events (deep vein thrombosis or pulmonary embolus) (include events that occurred between admission and day 7*)

☐ Yes
☐ No
☐ Unknown

*ie, mark yes if a DVT occurred on day 4, for example.

Section 2: ARDS (For a diagnosis of ARDS, patient must meet all 3 criteria below)

Criterion 1:

Has the patient developed symptoms within 7 days of an ARDS risk factor in addition to the severe burn?

☐ Yes
☐ No
☐ Unknown

If yes, choose all that apply:

☐ Pneumonia
☐ Non-pulmonary sepsis
☐ Non-cardiogenic shock
☐ Aspiration of gastric contents
☐ Drug overdose
☐ Major trauma in addition to the burn injury
☐ Multiple transfusions or TRALI
☐ Pulmonary contusion
☐ Pulmonary vasculitis
☐ Pancreatitis
☐ Drowning
☐ Inhalation injury

Are there objective data (e.g. echocardiography) to rule out hydrostatic edema due to heart failure? ☐ Yes ☐ No ☐ Unknown	**Describe:**

Criterion 2:

Does the patient have bilateral chest radiograph (CXR) or CT scan opacities, not fully explained by effusions, lobar/lung collapse, or nodules? ☐ Yes ☐ No ☐ Unknown	**Describe if yes:**

Criterion 3:

Is there an oxygenation abnormality, i.e., $PaO_2/FiO_2 < 300$?
☐ Yes
☐ No
☐ Unknown

What is the PaO_2? (mmHg)	**What is the FiO_2? (fraction)**	**Calculate PaO_2/FiO_2 =**

Is the patient intubated? ☐ Yes ☐ No ☐ Unknown	**If yes, what is the PEEP? (cmH_2O)**
Is the patient on non-invasive ventilation? ☐ Yes ☐ No ☐ Unknown	**If yes, what is the CPAP? (cmH_2O)**

Scoring:

Choose the correct level of ARDS:
☐ None (oxygenation: $PaO_2/FiO_2 > 300$)
☐ Mild ARDS (oxygenation: $200 < PaO_2/FiO_2 \leq 300$ with PEEP or CPAP ≥ 5 cmH_2O)
☐ Moderate ARDS (oxygenation: $100 < PaO_2/FiO_2 \leq 200$ with PEEP ≤ 5 cmH_2O)
☐ Severe ARDS (oxygenation: $PaO_2/FiO_2 \leq 100$ with PEEP ≥ 5 cmH_2O)

Section 3: SOFA Score: Day 7

Instructions: For each data element, use worst values from last 24 hours.

Note: The GCS should be administered in the absence of sedation (ie, during a daily sedation break) if possible.

(N/A: mark this box ☐ and skip the questions below if patient is no longer in hospital)

PaO_2/FiO_2, mmHg:

☐ ≥400 (0)
☐ 300-399 (+1)
☐ 200-299 (+2)
☐ ≤199 and NOT mechanically ventilated (+2)
☐ 100-199 and mechanically ventilated (+3)
☐ <100 and mechanically ventilated (+4)

Platelets, $\times 10^3/\mu L$:

☐ ≥150 (0)
☐ 100-149 (+1)
☐ 50-99 (+2)
☐ 20-49 (+3)
☐ <20 (+4)

Glasgow Coma Scale Score:

☐ 15 (0)
☐ 13-14 (+1)
☐ 10-12 (+2)
☐ 6-9 (+3)
☐ <6 (+4)

Bilirubin, mg/dL (µmol/L):
(assume normal, or <1.2 (<20))

☒ <1.2 (<20) (0)
☐ 1.2–1.9 (20-32) (+1)
☐ 2.0–5.9 (33-101) (+2)
☐ 6.0–11.9 (102-204) (+3)
☐ ≥12.0 (>204) (+4)

Mean arterial pressure OR administration of vasoactive agents required (listed doses are in units of mcg/kg/min):

☐ No hypotension (0)
☐ MAP <70 mmHg (+1)
☐ Dopamine ≤5 or dobutamine (any dose) (+2)
☐ Dopamine >5, epinephrine ≤0.1, or norepinephrine ≤0.1 (+3)
☐ Dopamine >15, epinephrine >0.1, or norepinephrine >0.1 (+4)

Creatinine, mg/dL (or urine output):

☐ <1.2 (0)
☐ 1.2–1.9 (+1)
☐ 2.0–3.4 (+2)
☐ 3.5–4.9 or UOP <500 mL/day) (+3)
☐ ≥5.0 or UOP <200 mL/day (+4)

Add the selected values for the total SOFA Score (max score is 24):

PROPOLIS Medical Record Data Abstraction Form: Day 28

Instructions: Collect the following information from the medical record at Day 28, regardless of status of participant at Day 28 (ie, collect this information for those who died or were discharged prior to Day 28).

Name of staff member screening and extracting medical record data: _____

Screening date (mm/dd/yyyy): _____

Section 1: Day 28		
Date discharged from BICU:	**Date discharged from hospital:**	
If the patient was on the ventilator more than once, enter on and off date for each ventilator instance. Ventilator day is defined as each 24 hour period with any mechanical ventilation.		
Date on ventilator:	**Date on ventilator:**	**Date on ventilator:**
Date off ventilator:	**Date off ventilator:**	**Date off ventilator:**

Discharge disposition:	**If other, explain:**
☐ Home or self care ☐ Skilled nursing facility (SNF) ☐ Long-term acute care/long-term care hospital ☐ Home health care ☐ Died ☐ Against medical advice (AMA) ☐ Inpatient rehabilitation ☐ Other acute care hospital ☐ Other ☐ Unknown	

PROPOLIS Self-Report Data Collection Form: 6-months Post-Burn

On the next page is the PROMIS Global profile. This can be collected from participants by interview (in person or over the phone) or by paper and pencil.

Name of staff member interviewing or entering data: _____

Section 1: Follow-up Information	
Date of data collection *(mm/dd/yyyy)*:	**Status of follow-up assessment:** ☐ Some or all assessment done ☐ Death due to burn related complications ☐ Death due to non-burn related complications ☐ Unable to locate ☐ Withdrew ☐ Unable to test/med comp/incapable of responding ☐ Failed to respond
Method of administration: ☐ In person interview ☐ Phone interview ☐ Mailed form ☐ Form filled out by participant in clinic	

Study ID #: _____

Please respond to each question or statement by marking one box per row

	Excellent	Very good	Good	Fair	Poor
In general, would you say your health is……..	☐	☐	☐	☐	☐
In general, would you say your quality of life is…….	☐	☐	☐	☐	☐
In general, how would you rate your physical health?.....	☐	☐	☐	☐	☐
In general, how would you rate your mental health, including your mood and your ability to think?.....	☐	☐	☐	☐	☐
In general, how would you rate your satisfaction with your social activities and relationships?.....	☐	☐	☐	☐	☐
In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.).....	☐	☐	☐	☐	☐

	Completely	Mostly	Moderately	A little	Not at all
To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?.....	☐	☐	☐	☐	☐

In the past 7 days…	Never	Rarely	Sometimes	Often	Always
How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?.....	☐	☐	☐	☐	☐

In the past 7 days…	None	Mild	Moderate	Severe	Very Severe
How would you rate your fatigue on average?.....	☐	☐	☐	☐	☐

How would you rate your pain on average?.....

☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

0 1 2 3 4 5 6 7 8 9 10

No pain **Worst pain imaginable**

Footnotes

1. Deep electric injury: high voltage electric injury causing gross myoglobinuria (clinical diagnosis)

2. Associated non-thermal injuries: defined as a requirement (because of traumatic injury) for blood transfusion, major intracavitary surgery (craniotomy, thoracotomy, laparotomy), angioembolization, or endovascular surgery during the first 24 hours after injury

e-Table 1. Dose equivalents of vasopressors

Vasopressor	Norepinephrine equivalent dose
Norepinephrine	1
Epinephrine	1
Dopamine(E1, E2)	0.01
Vasopressin(E3)	5*
Phenylephrine(E4)	0.45

*Approximate conversion of vasopressin dose in units/min to equivalent norepinephrine dose in mcg/kg/min, normalized to 100kg body weight

3. Patient already receiving "rescue procedures": defined as albumin infusion, CRRT, TPE, or high-dose ascorbic acid

4. Congestive heart failure (NYHA Class IV): Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

5. KDIGO grading of Acute Kidney Injury: see Table.

2.1.1: AKI is defined as any of the following (***Not Graded***):
- Increase in SCr by $\geqslant$0.3 mg/dl ($\geqslant$26.5 µmol/l) within 48 hours; or
- Increase in SCr to $\geqslant$1.5 times baseline, which is known or presumed to have occurred within the prior 7 days; or
- Urine volume $<$0.5 ml/kg/h for 6 hours.

2.1.2: AKI is staged for severity according to the following criteria (Table 2). (***Not Graded***)

Table 2 | Staging of AKI

Stage	Serum creatinine	Urine output
1	1.5–1.9 times baseline OR $\geqslant$0.3 mg/dl ($\geqslant$26.5 µmol/l) increase	$<$0.5 ml/kg/h for 6–12 hours
2	2.0–2.9 times baseline	$<$0.5 ml/kg/h for $\geqslant$12 hours
3	3.0 times baseline OR Increase in serum creatinine to $\geqslant$4.0 mg/dl ($\geqslant$353.6 µmol/l) OR Initiation of renal replacement therapy OR, In patients $<$18 years, decrease in eGFR to $<$35 ml/min per 1.73 m^2	$<$0.3 ml/kg/h for $\geqslant$24 hours OR Anuria for $\geqslant$12 hours

6. Norepinephrine Equivalents: see above Table.