Tulane Human Research Protection Office
Institutional Review Boards
Biomedical
Social Behavioral
FWA00002055

DATE: January 10, 2022

TO: Sharven Taghavi
FROM: Tulane University Biomedical IRB

STUDY TITLE: Examining Nationwide Trends of Aggressive Resuscitation Protocols for Catastrophic Brain Injuries

REF #: 2021-1794
SUBMISSION TYPE: Initial Submission

ACTION: **EXEMPT**

On January 6, 2022, the Tulane University Biomedical IRB provided a review and Exempt determination for the initial submission of this study, in accordance with the appropriate federal regulations.

The following items were submitted as part of the submission:

- Conditional RRC approval.pdf (Other)
- IRB aggressive resuscitation.docx (Study Protocol)
- Tulane IRB Data Collection Tool.docx (Data Collection Tool)
- UMCNO Data Use Authorization.pdf (Data Use Agreement)

This study is approved for the local enrollment of 50 subjects.

Exempt studies are subject to institutional oversight including reviews and audits by the Human Research Protection Program. Please submit any proposed changes to the research that could potentially change the exempt status prior to implementation, unless a change is necessary to avoid immediate harm to subjects. If subject safety becomes an issue, please notify the Tulane University Human Research Protection Office (HRPO) as soon as possible.

Please submit any unanticipated problems involving risk to subjects or others, deviations from the approved research, non-compliance, and complaints to the IRB in accordance with Tulane University Human Research Protection Program (HRPP) Standard Operating Procedures (SOPs). Please contact the HRPO via irbmain@tulane.edu or (504) 988-2665 if you have questions and/or concerns regarding reporting events.

If your study is supported in whole or in part by a federal grant, please note that Federal regulations prohibit the use of Federal funds for human subject research that is not conducted under current IRB approval. Loss of IRB approval for this study due to lapse, suspension or termination will be communicated by the Tulane IRB to Tulane's Office of Grants and Contracts Accounting, which may result in an administrative hold being placed on the related grant(s). Therefore, to avoid an interruption in

research activity, including use of coded, identifiable human data or biospecimens, and access to grant funds it is critical that IRB approval for the study be maintained.

Please notify the IRB within 30 days of completion of all study activities and data analysis by submitting a Study Closure Form.

The Principal Investigator is responsible for being familiar with and complying with Tulane University HRPP SOPs found at https://research.tulane.edu/hrpo. Please do not hesitate to contact our office with any questions or concerns.

We encourage investigators and research staff to provide feedback about the IRB review process, our website, and any other aspects of the HRPP that will help us to identify improvements we can make. You can complete this form in an anonymous manner at HRPO/IRB Feedback Survey.

Sincerely,

Tulane University Human Research Protection Office

Please note that the actual signature by the IRB Chair(s) is not required for this document to be effective. IRBManager generates this letter pursuant to the IRB Chair's electronic signature and approval. This process is consistent with Federal Regulations and Tulane Standard Operating Policies with respect to the IRB and Human Research Protection Office, which consider electronically generated documents as official notices to sponsors and others of approval, disapproval or other IRB decisions. Please refer to Tulane's Electronic Signatures and Records Policy by visiting the HRPO website at https://research.tulane.edu/hrpo.

Eastern Association for the Surgery of Trauma
Advancing Science, Fostering Relationships, and Building Careers

EAST MULTICENTER STUDY
DATA COLLECTION TOOL

***Multicenter Study**:* Prospective Observational Trial Examining Nationwide Trends of Aggressive Resuscitation Protocols for Catastrophic Brain Injuries

Enrolling Center: _____
Enrolling Co-investigator: _____

Demographics / Injury Variables:

Age: _____ Gender:_____
Race/Ethnicity:_____
Comorbidities:_____
Advance directive pre- and post- admission: _____
Withdrawal of care YES / NO
DNR status (pre- and post-admission) : _____

Mechanism of initial Head injury:
Blunt: YES / NO
Penetrating: YES / NO
Type of injury (MVC, fall, GSW, etc.): _____

Intent of initial Head injury:
Assault YES / NO
Self-Inflicted YES / NO
Accident YES / NO
Other YES / NO
Unknown YES / NO

ISS: _____ AIS Head: _____ AIS Chest: _____ AIS Abdomen: _____

Other injuries: _____

Initial In-Hospital Neurocognitive Exam:

GCS: _____ GCS-E: _____ GCS-V: _____ GCS-M: _____
CT brain findings (Marshall classification): _____

Initial In-Hospital Vitals:

SBP: _____ DBP: _____ MAP: _____ RR: _____ HR: _____ Temperature: _____

Hospital Course:

ED interventions: _____
Neurosurgical Interventions: _____ Other Surgeries: _____ Hospital LOS: _____ ICU LOS: _____
Vent Days: _____
Placement of:
Tracheostomy: YES / NO
Feeding Tube: YES / NO

Therapy:

Institution or ICU protocol for catastrophic brain injury in place YES / NO
Institution or ICU protocol for catastrophic brain injury initiated YES / NO
If catastrophic brain protocol exists and not initiated, reason(s) for this(ex. injury severity, patient age, advance Directive/DNR in place, etc.) : _____
Patient status triggering initiation of protocol use (hypotensive, massive hemorrhage, etc.) : _____
Therapy administered in accordance with institutional protocol: _____
Presence of an order set in the EMR?: _____
Order set used?: YES / NO

Transfusion Information:

Resuscitative:
# of units whole blood transfused during resuscitation: _____ total administered: _____
# of units packed red blood cells transfused during resuscitation: _____ total administered: _____
# of units platelets transfused during resuscitation: _____ total administered: _____
# of units fresh frozen plasma transfused during resuscitation: _____ total administered: _____
# of units cryoprecipitate transfused during resuscitation: _____ total administered: _____
# of units fluids transfused first during resuscitation: _____ total administered: _____
Type of fluid(s) administered first during resuscitation: _____

Post-Resuscitative:
# of units whole blood transfused first 24 hrs: _____ total administered: _____
# of units packed red blood cells transfused first 24 hrs: _____ total administered: _____
# of units platelets transfused first 24 hrs: _____ total administered: _____
# of units fresh frozen plasma transfused first 24 hrs: _____ total administered: _____
# of units cryoprecipitate transfused first 24 hrs: _____ total administered: _____
# of units fluids transfused first 24 hrs: _____ total administered: _____
Type of fluid(s) administered first 24 hrs: _____

Amount of time between ED arrival and initiation of protocol (mins): _____
Time between injury and administration of):
whole blood: _____
packed red blood cells: _____
platelets: _____
fresh frozen plasma: _____
cryoprecipitate: _____
fluids: _____

Hormone Replacement Therapy Agents Administered:

Methylprednisone YES / NO dosage:___ frequency/duration: __ total administered: __ adverse effect(s): __
Vasopressin YES / NO dosage:___ frequency/duration: __ total administered: __ adverse effect(s): __
Insulin YES / NO dosage:___ frequency/duration: __ total administered: __ adverse effect(s): __
T3 YES / NO dosage:___ frequency/duration: __ total administered: __ adverse effect(s): __
T4 YES / NO dosage:___ frequency/duration: __ total administered: __ adverse effect(s): __
Dopamine YES / NO dosage:___ frequency/duration: __ total administered: __ adverse effect(s): __
Other YES / NO dosage:___ frequency/duration: __ total administered: __ adverse effect(s): _

Explain adverse effects of hormone replacement if YES above: _____

Hormone replacement given as a drip: YES / NO and for how long: _____
Hormone replacement given as a bolus YES / NO and how many: _____

Time between injury and administration of replaced hormone(s):
Methylprednisone: _____
Vasopressin: _____
Insulin: _____
T3: _____
T4: _____
Dopamine: _____
Other: _____

Operative management variables:
Time from injury to initial operation (in hours): _____
Indication for use of open abdominal management (check one that best applies)
_____ Damage control
_____ To facilitate early re-exploration and urgent/emergent re-evaluation (i.e. assessment of bowel viability)
_____ Decompression of abdomen in setting of elevated ICP
_____ Other:_____

Operative variables at time of surgery:
Peri-operative antibiotics (defined as antibiotics initiated during operation or started within 24 hours after the completion of initial procedure) (Circle one): Yes No (Type:_____)

Blood loss: _____cc
Intra-operative crystalloid given: _____cc
Total Intra-operative blood products given: _____cc
PRBC volume: _____cc
FFP volume: _____cc
Platelet volume: _____cc
Intra-operative non-blood colloid given: _____cc

Total fluid balance from OR _____**cc**

Damage control indicators present during operation? (Check all that apply)
_____ Clinical coagulopathy
_____ Acidosis (pH?_____)
_____ Hypothermia (temp < 35 C)

Post-operative course:
Fluid requirements first **24 hours** after surgery (total fluids):_____cc
Colloid: _____cc
Crystalloid: _____cc
Fluid requirements first **48 hours** after surgery (total fluids):_____cc
Colloid: _____cc
Crystalloid: _____cc
Were antibiotics utilized post-operatively (circle one): No Yes Type:_____
Dosing interval:_____
Duration of use:_____

Mechanical Ventilation:
Unit where ventilated: _____
Ventilation mode utilized: _____
Maximum peak airway pressure observed:_____
Hours on vent: _____

Biomarker Levels:

Creatinine	Peak:_____ At time of donation or death without donation:_____
Troponin	Peak:_____ At time of donation or death without donation:_____
Bilirubin	Peak:_____ At time of donation or death without donation:_____
Lipase	Peak:_____ At time of donation or death without donation:_____
ALT	Peak:_____ At time of donation or death without donation:_____
AST	Peak:_____ At time of donation or death without donation:_____
PaO2	Peak:_____ At time of donation or death without donation:_____
FiO2	Peak:_____ At time of donation or death without donation:_____
Ejection Fraction	Peak:_____ At time of donation or death without donation:_____

Outcomes:

Brain Death? YES / NO
Time From Admission to Death: _____
Referral for Organ Donation Made to Organ Procurement Organization/Agency (OPO)? YES / NO
Unit Where Referral Sent From: ED, ICU, other
Next-of-kin Approached for Organ Donation: YES / NO
Unit Where Next-of-kin Was Approached: _____
Next-of-kin Consent: YES / NO
Organs Donated: YES / NO
If organs not donated, list reason for non-donation: _____
List Organs Donated: _____
Time in Hospital: _____

Complications:
Medication-Specific:
_____ Cardiac arrythmia
_____ Hypertension
_____ Tachycardia
_____ Seizure
_____ Other

In-Hospital Events:
_____ Acute Kidney Injury (AKI)
_____Cardiopulmonary Arrest
_____ Myocardial Infarction (MI)
_____ Pneumonia
_____ Respiratory Failure
_____ Acute Respiratory Distress Syndrome (ARDS)
_____ Sepsis
_____ Unplanned OR Intervention
_____ Venous Thromboembolic Event (VTE)
_____ Diabetes Insipidus
_____ Hyperglycemia
_____ Other

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EAST MULTICENTER STUDY
DATA DICTIONARY

Prospective Observational Trial Examining Nationwide Trends of Aggressive Resuscitation Protocols for Catastrophic Brain Injuries

Data Entry Points and appropriate definitions / clarifications:

Entry space	Definition / Instructions
Standard Study Questions	
Admit Date	Admission date of the patient enrolled
Admit Time	Admission time of the patient enrolled
Age	Age of patient enrolled
Case Information	
Gender	Gender of Patient enrolled
Advance directive (pre- and post- admission)	Presence of advance directive on file or provided by/for patient
Withdrawal of care	Discontinuation of mechanical ventilation and other artificial patient support
DNR status	Presence (or lack-thereof) and contents of patient's do not resuscitate order
Mechanism of initial Injury	
Blunt	Single choice for best description of blunt mechanism (if penetrating mechanism proceed to next data point) Options include: MVC, Auto vs. Peds (Pedestrian), Fall, Assault, MCC (Motorcycle Collision / Crash) Machinery Other
Penetrating	Single choice for best description of penetrating mechanism. Options include:

	GSW (Gunshot wound) Shotgun (Shotgun wound) Stab (Stab Wound) Other
ISS	Numerical value for calculated ISS (ISS = Injury Severity Score)
AIS Head	Numerical Value for AIS body region = Head (AIS = Abbreviated Injury Score)
AIS Chest	Numerical Value for AIS body region = Chest (AIS = Abbreviated Injury Score)
AIS Abdomen	Numerical Value for AIS body region = Abdomen (AIS = Abbreviated Injury Score)

Hospital Course

ED interventions	Procedures performed in the Emergency Department by any specialty team

Management Variables

Time Between Injury and Administration of Replaced Hormone(s)	Time from injury to initial hormone replacement start (in minutes)

Operative variables at time of surgery:

Peri-operative antibiotics	defined as antibiotics intiated within 2 hours prior or during operaton, or antibiotics started within 24 hours after completion of initial operation) Answer options: Yes or No, Type if yes
Intra-operative blood loss (cc)	Recorded intra-operative blood loss (in cc's)
Intra-operative crystalloid given (cc)	Recorded intra-operative crystalloid given (in cc's)
PRBC volume (cc)	PRBC (Packed Red Blood Cells) administered during the initial operation (in cc's)
FFP volume (cc)	FFP (Fresh Frozen Plasma) administered during the initial operation (in cc's)
Platelet volume (cc)	Platelet volume administered during the intitial operation (in cc's)
Total intra-operative blood products given (cc)	Total intra-operative blood products given during the initial operation (PRBC, FFP, Platelets, cryoprecipitate) (in cc's)
Intra-operative non-blood colloid given (cc)	Total intra-operative non-blood colloid given during the initial operation (albmumin, hespan

	hextend or other colloid) (in cc)
Total fluid balance from OR	Total fluid administered (crystalloid, blood product, and colloid) – intra-operative blood loss (in cc). If a negative number annotate with a negative (-) sign

Damage control indicators present during operation

Clinical coagulopathy	Clinical (not laboratory) assessment of clinical coagulopathy during initial operation (persistent non-surgical bleeding, etc.) – Check if present
Acidosis	Acidosis defined as pH <7.35 during operation Check if present
Lowest pH	Lowest recorded pH during operation – Free text entry of value.
Hypothermia	Hypothermia (defined as intra-operative Temperature < 35.0 Celsius) – Check if present

Post-operative course

Fluid requirements first 24 hours after surgery

Colloid (cc)	Free text entry of total colloid requirements within first 24 hours of surgery. For this section, colloids include all blood products as well as non-blood product colloids (ex. Albumin, hespan, hextend) (in cc)
Crystalloid (cc)	Free text entry of total crystalloids infured in the 24 hours following surgery (in cc)
Total fluids (cc)	Total colloid and crystalloid infused the first 24 hours after surgery (in cc)

Fluid requirements 48 hours after surgery

Colloid (cc)	Free text entry of total colloid requirements within first 48 hours of surgery. For this section, colloids include all blood products as well as non-blood product colloids (ex. Albumin, hespan, hextend) (in cc)
Crystalloid (cc)	Free text entry of total crystalloids infured in the 48 hours following surgery (in cc)
Total fluids (cc)	Free text entry of total colloid and crystalloid infused the first 48 hours after surgery (in cc)
Antibiotics utilized post-operatively	Yes/No, dosing interval and duration of use

Mechanical Ventilation

Ventilation mode post-operatively	Free text entry of ventilation mode utilized. Abbreviations appropriate (examples: SIMV for spontaneous intermittent mechanical ventilation, APRV, or CMV, etc)
Ventilation mode used	Ex. positive pressure, negative pressure,

Maximum peak airway pressure	Free text entyry of peak airway pressure encountered at any point during the use of mechanical ventilation post-operatively (mm/Hg)
Hours on Vent	Number of hours patient spent ventilated in total

Outcomes

Brain death	As determined by care team including neurosurgery, neurology, trauma surgery, etc.
Time from admission to death	Time in minutes from admission to hospital to determination of death
Referral for Organ Donation Made to Organ Procurement Organization (OPO)	Yes/No, whether patient was referred as a potential donor to OPO
Unit Where Referral Sent From	Unit where potential donor referral was made from (ED, ICU, other)
Next-of-kin Approached for Organ Donation	YES / NO, Whether OPO approached next-of-kin regarding organ donation
Unit Where Next-of-kin Was Approached	Unit where potential donor referral was made from (ED, ICU, other)
Next-of-kin Consent	YES / NO, Was approval for organ donation given from next-of-kin?
Organs Donated	YES / NO, Were organs donated successfully?
List Organs Donated	Organs donated (list name and number, ex. pair of lungs= 2 lungs)
Time in Hospital	Time spent in hospital by patient from admission to death or discharge to OPO or organ donation

Complications (check all that apply)

Definitions of complications included in this section:

Medication-Specific:

Cardiac arrythmia	Check if applies. Cardiac rhythm abnormality caused by medication administered by care team
Hypertension	Check if applies. SBP > 140 or DBP >90
Hypotension	Check if applies. SBP < 100 or MAP < 65
Tachycardia	Check if applies. HR >100 beats/minute
Seizure	Check if applies. Select type (ex. focal, primary generalized, clonic-tonic)

In-Hospital Events:

Acute Renal Injury	Check if applies. Defined for the purpose of this study as elevation of serum creatinine greater or equal to 2.0 mg/dL during hospitalization in patient without antecedent renal dysfunction.
Cardiopulmonary Arrest	Check if applies. Loss of heart function, breathing, consciousness
Pneumonia	Check if applies, define type. VAP = Ventilator-associated

	Pneumonia, hospital-acquired pneumonia occurring in a patient who was intubated and ventilated at the time of or within 48 hours before onset of pneumonia.
Respiratory Failure	Check if applies. Inadequate oxygenation causing hypoxia or hypoxemia
Acute Respiratory Distress Syndrome (ARDS)	Check if applies. ARDS = Acute respiratory distress syndrome. Definition(s) below: ARDS: ARD Net definitions will be utilized – (ARDS – PaO2/FiO2 < 200; must have appropriate radiographic findings)
Sepsis	Check if applies. Definition below. Sepsis: Has a confirmed infectious process AND two or more of the following: 1. Body temperature < 36 degrees Celsius (97 F) or > 38 C (100 F) 2. Heart rate > 100 bpm 3. Respiratory rate > 20 breaths per minute or, on blood gas, PaCO2 of less than 32 mm Hg 4. White blood cell count > 4,000 cells/mm^3 or > 12,000 cells/mm^3 or greater than 10% and forms (immature wbc)
Unplanned OR Intervention	Check if applies. List unplanned operation and time after admission of intervention (in minutes)
Venous Thromboembolic Event	Check if applies. DVT = Deep Vein Thrombosis PE = Pulmonary embolism. Diagnosis must be confirmed radiographically (Ultrasound, Computed tomography, venography, etc.)
Diabetes Insipidus	Check if applies. Urine osmolality < 300 mOsmol/kg with polyuria
Hyperglycemia	Check if applies. Serum glucose > 200 mg/dL.
Other	