VANDERBILT

RE: IRB #231109 "Mixed-Methods Analysis of Care Variation in Severe Traumatic Brain Injury"

Dear Shayan Rakhit, M.D.:

A sub-committee of the Institutional Review Board reviewed the research application identified above. The sub-committee determined the study poses minimal risk to participants, and the application is approved under 45 CFR 46.110 categories (F) (5), (6), and (7). Approval is extended for the Protocol dated 7/14/23 and the Grant entitled "Interdisciplinary Training in Injury and Critical Illness " for Principal Investigator Shayan Rakhit, M.D..

The Consent Form(s) have been stamped with the approval date and this copy should be used when obtaining the participant's signature.. Federal regulations require that the original copy of the participant's consent be maintained in the principal investigator's files and that a copy be given to the subject at the time of consent. An additional record (i.e., case report form, medical record, database, etc.) of the consent process should also be maintained in a separate location for documentation purposes.

As the Principal Investigator, you are responsible for the accurate documentation, investigation and follow-up of all possible study-related adverse events and unanticipated problems involving risks to participants or others. The IRB Adverse Event/Unanticipated Problem reporting policy III.L is located on the IRB website at http://www.mc.vanderbilt.edu/irb/.

If this trial requires registration as a clinical trial, accrual cannot begin until this study has been registered at clinicaltrials.gov and a National Clinical Trial Number (NCT) provided. Please provide the NCT# to the IRB as soon as it is obtained. If an approval is required from an additional source other than the Vanderbilt IRB, this must be obtained prior to study initiation. These approvals may include, but are not limited to CRC, SRC, IND, IDE.

NEW REQUIREMENT: For research that meets the definition of a clinical trial and is supported by a federal department or agency, one IRB approved informed consent document used to enroll subjects must be posted on a publicly available federal website (clinicaltrials.gov). The consent document must be posted no later than 60 days after the last study visit of any subject.

While federal regulations no longer require reporting of study activity information (continuing review) for minimal risk studies that are not FDA regulated, VUMC requires reporting of enrollment numbers to document participant accrual for research studies. Any changes to the research study must be presented to the IRB for approval prior to implementation.

Note: IRB approval is not extended to the materials to be used in Phases III and IV of this study. It is the expectation of the IRB that these materials will be submitted to the IRB for review and approval prior to implementation.

DATE OF IRB APPROVAL: 10/5/2023

Sincerely,

Jennifer Ledford PhD, Vice Chair
Institutional Review Board
Integrated Sciences Committee

Electronic Signature: Jennifer Ledford/VUMC/Vanderbilt : (ecbb1b546ded41c021a4c3c5507fadfa)
Signed On: 10/10/2023 10:46:45 AM CDT

VANDERBILT

Regulatory Determinations

Regulations
[**x**] **DHHS- 45 CFR 46**
[ ] FDA- 21 CFR 50, 56
[ ] HRP review of a study where Vanderbilt is not the IRB of Record

DHHS- 45 CFR 46 Type (if FDA-Regulated does not apply)
[**x**] **2018 Revised Common Rule**
[ ] Pre-2018 Common Rule

Consent
[**x**] **Consent (45 CFR 46.116(a-c))**
[**x**] **Waiver of Documentation (45 CFR 46.117(c)(1)**
[ ] Alteration of the Consent Process (45 CFR 46.116(f)(2))
[ ] Waiver of consent/process (45 CFR 46.116(f)(1))
[ ] Exception from Informed Consent (21 CFR 50.24) (Note: FDA regulated research only)

Privacy Board Review
[**x**] **HIPAA Authorization (45 CFR 164.510)**
[ ] HIPAA Waiver (45 CFR 164.512)
[ ] HIPAA review is not required
[ ] Exempt Study meeting 45 CFR 46.104(d)(4)(iii): The data in this study is subject to 45 CFR 160 and 164, the Investigator is expected to: protect the identifiers from improper use and disclosure; destroy the identifiers at the earliest opportunity; and assure that the PHI will not be reused or disclosed to any other person or entity, except as required by law.

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

EAST MULTICENTER STUDY
DATA COLLECTION TOOL

Multicenter Study: Mixed-Methods Analysis of Care Variation in Severe Traumatic Brain Injury

Enrolling Center: _____
Enrolling Co-investigator: _____

Please provide center-level summary statistics (mean, median, range, numbers, and/or percentages, as specified) for the following variables for patients, age 18 and above, and presenting to your center from July 1, 2022 - June 30, 2023 with severe traumatic brain injury (GCS ≤ 8). All variables are from the National Trauma Data Standard (NTDS) and should exist in your registry.

Demographic Variables:

Age (years):
mean___ sd___ median___ range___

Sex:
Female: number___ percentage___
Male: number___ percentage___

Race:
Asian: number___ percentage___
Native Hawaiian or Other Pacific Islander: number___ percentage___
Other Race: number___ percentage___
American Indian: number___ percentage___
Black: number___ percentage___
White: number___ percentage___

Ethnicity:
Hispanic or Latino: number___ percentage___
Not Hispanic or Latino: number___ percentage___

Primary method of payment:
Medicaid: number___ percentage___
Not billed (any reason): number___ percentage___
Self-pay: number___ percentage___
Private/commercial insurance number___ percentage___
Medicare: number___ percentage___
Other government: number___ percentage___
Other: number___ percentage___

Pre-existing Health Status Variables:

Anticoagulant therapy:
Yes: number___ percentage___
No: number___ percentage___

Bleeding disorder:
Yes: number___ percentage___
No: number___ percentage___

Cerebral vascular accident:
Yes: number___ percentage___
No: number___ percentage___

Chronic obstructive pulmonary disease:
Yes: number___ percentage___
No: number___ percentage___

Chronic renal failure:
Yes: number___ percentage___
No: number___ percentage___

Cirrhosis:
Yes: number___ percentage___
No: number___ percentage___

Congestive heart failure:
Yes: number___ percentage___
No: number___ percentage___

Currently receiving chemotherapy for cancer:
Yes: number___ percentage___
No: number___ percentage___

Dementia:
Yes: number___ percentage___
No: number___ percentage___

Functionally dependent health status:
Yes: number___ percentage___
No: number___ percentage___

Myocardial infarction
Yes: number___ percentage___
No: number___ percentage___

Pregnancy
Yes: number___ percentage___
No: number___ percentage___

Injury Variables:

ICD-10 primary external cause code (please list)
(for each): number___ percentage___

ISS:
mean___ sd___ median___ range___

AIS Head:
mean___ sd___ median___ range___

AIS Face:
mean___ sd___ median___ range___

AIS Neck:
mean___ sd___ median___ range___

AIS Thorax:
mean___ sd___ median___ range___

AIS Abdomen:
mean___ sd___ median___ range___

AIS Neck:
mean___ sd___ median___ range___

AIS Spine:
mean___ sd___ median___ range___

AIS Upper Extremity:
mean___ sd___ median___ range___

AIS Lower Extremity:
mean___ sd___ median___ range___

AIS External:
mean___ sd___ median___ range___

Initial ED/hospital GCS – total
mean___ sd___ median___ range___

Initial ED/hospital GCS – motor
mean___ sd___ median___ range___

Highest GCS – total
mean___ sd___ median___ range___

Highest GCS – motor
mean___ sd___ median___ range___

Initial ED/hospital pupillary response
Both reactive: number___ percentage___
One reactive: number___ percentage___
Neither reactive: number___ percentage___
Missing: number___ percentage___

Midline shift – motor
Yes: number___ percentage___
No: number___ percentage___
Not imaged: number___ percentage___
Missing: number___ percentage___

Management Variables:

Cerebral monitor:
- Intraventricular drain/catheter: number___ percentage___
- Intraparenchymal pressure monitor: number___ percentage___
- Intraparenchymal oxygen monitor: number___ percentage___
- Jugular venous bulb: number___ percentage___
- None: number___ percentage___
- Missing: number___ percentage___

Decompressive neurosurgery:
- Craniectomy: number___ percentage___
- Craniotomy: number___ percentage___
- None: number___ percentage___
- Missing: number___ percentage___

Surgery for hemorrhage control:
- None: number___ percentage___
- Laparotomy: number___ percentage___
- Thoracotomy: number___ percentage___
- Sternotomy: number___ percentage___
- Extremity: number___ percentage___
- Neck: number___ percentage___
- Mangled extremity/traumatic amputation: number___ percentage___
- Other skin/soft tissue: number___ percentage___
- Extraperitoneal pelvic packing: number___ percentage___
- Missing: number___ percentage___

Angiography for hemorrhage control:
- None: number___ percentage___
- Angiogram only: number___ percentage___
- Angiogram with embolization only: number___ percentage___
- Angiogram with stenting : number___ percentage___
- Missing: number___ percentage___

Hospital Event Variables:

Acute respiratory distress syndrome:
- Yes: number___ percentage___
- No: number___ percentage___

Cardiac arrest with CPR:
- Yes: number___ percentage___
- No: number___ percentage___

Myocardial infarction:
- Yes: number___ percentage___
- No: number___ percentage___

Pulmonary embolism:
- Yes: number___ percentage___
- No: number___ percentage___

Severe sepsis:
- Yes: number___ percentage___
- No: number___ percentage___

Stroke/CVA:
Yes: number___ percentage___
No: number___ percentage___

Ventilator-associated pneumonia (VAP)
Yes: number___ percentage___
No: number___ percentage___

Outcome Variables:

Total ICU length of stay (days):
mean___ sd___ median___ range___

Total ventilator days:
mean___ sd___ median___ range___

Hospital discharge disposition:
Short-term general hospital as inpatient: number___ percentage___
Intermediate care facility: number___ percentage___
Home with home health: number___ percentage___
Short-term general hospital as inpatient: number___ percentage___
Left against medical advice: number___ percentage___
Deceased: number___ percentage___
Home or self-care (routine discharge): number___ percentage___
Skilled nursing facility (SNF): number___ percentage___
Hospice care: number___ percentage___
Court/law enforcement: number___ percentage___
Inpatient rehab or designated unit: number___ percentage___
Long Term Care Hospital (LTCH): number___ percentage___
Psychiatric hospital or unit: number___ percentage___
Other type of institution not previous defined: number___ percentage___

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

EAST MULTICENTER STUDY
DATA DICTIONARY

Mixed-Methods Analysis of Care Variation in Severe Traumatic Brain Injury

The following variables refer to center-level summary statistics of eligible patients during the time period. Definitions adapted from National Trauma Data Standard (NTDS). Please see NTDS for more specific instructions for the relevant variable.

Data Entry Points and appropriate definitions / clarifications:

Entry space	Definition / Summary Statistic
Demographic Variables	
Age	Age of patients (years) / mean, standard deviation, median, range
Sex	Sex of patients / number, percentage Options: Male Female
Race	Race of patients / number, percentage Options: Asian Native Hawaiian or Other Pacific Islander Other Race Black White
Ethnicity	Ethnicity of patients / number, percentage Options: Hispanic or Latino Not Hispanic or Latino
Primary method of payment	Race of patients / number, percentage Options: Medicaid Not billed (any reason) Self-pay Private Medicaid Other government Other

Pre-existing Health Status Variables:

Anticoagulant therapy	Documentation of medications that interfere with blood clotting / number, percentage Options: Yes No
Bleeding disorder	Conditions that result when blood cannot clot properly / number, percentage Options: Yes No
Cerebral vascular disorder	History prior to injury of cerebrovascular accident with persistent deficits / number, percentage Options: Yes No
Anticoagulant therapy	Documentation of medications that interfere with blood clotting / number, percentage Options: Yes No
Chronic obstructive pulmonary disease	Lung ailment characterized by persistent airflow blockage / number, percentage Options: Yes No
Chronic renal failure	Chronic renal failure requiring periodic dialysis or filtration / number, percentage Options: Yes No
Cirrhosis	End-stage liver disease / number, percentage Options: Yes No
Congestive heart failure	Inability of heart to pump sufficient quantity of blood / number, percentage Options: Yes No
Currently receiving chemotherapy for cancer /	number, percentage Options: Yes No

Dementia	Including senile or vascular dementia (e.g. Alzheimer's) / number, percentage Options: Yes No
Functionally dependent health status	Inability to complete age-appropriate daily-living activities / number, percentage Options: Yes No
Pregnancy	Confirmed by diagnostic tool or previously documented / number, percentage Options: Yes No

Injury Variables:

ICD-10 primary external cause code	Primary external cause code used to describe the mechanism that caused the injury event (please list) / For each cause code: number, percentage
ISS	Injury Severity Score (ISS) / mean, standard deviation, median, range
AIS Head	Abbreviated Injury Score (AIS) Head / mean, standard deviation, median, range
AIS Face	AIS Face / mean, standard deviation, median, range
AIS Neck	AIS Neck / mean, standard deviation, median, range
AIS Thorax	AIS Thorax / mean, standard deviation, median, range
AIS Abdomen	AIS Abdomen / mean, standard deviation, median, range
AIS Spine	AIS Spine / mean, standard deviation, median, range
AIS Upper Extremity	AIS Upper Extremity / mean, standard deviation, median, range
AIS Lower Extremity	AIS Lower Extremity / mean, standard deviation, median, range
AIS External	AIS External / mean, standard deviation, median, range
Initial ED/hospital GCS – total	First recorded Glagow Coma Scale (GCS) within 30 minutes of ED/hospital arrival / mean, standard deviation, median, range
Initial ED/hospital GCS – motor	First recorded GCS motor component within 30 minutes of ED/hospital arrival / mean, standard deviation, median, range
Highest GCS – total	Highest GCS on calendar day after hospital arrival / mean, standard deviation, median, range
Highest – motor	Highest GCS motor component on calendar day after hospital arrival / mean, standard deviation, median, range

Initial ED/hospital pupillary response	physiological response of the pupil size within 30 minutes or less of ED/hospital arrival / number, percentage Options: Both reactive One reactive Neither reactive
Midline shift	> 5mm shift of the brain past centerline within 24 hours of injury / number, percentage Options: Yes No Not imaged

Management Variables:

Cerebral monitor	Indicate all cerebral monitors placed / number, percentage Options: Intraventricular drain/catheter Intraparenchymal pressure monitor Intraparenchymal oxygen monitor Jugular venous bulb None Missing
Decompressive neurosurgery	Indicate operative neurosurgical procedures to decompress the cranium after traumatic brain injury / number, percentage Options: Craniectomy Craniotomy None Missing
Surgery for hemorrhage control:	Indicate first type of surgery to control hemorrhage / number, percentage Options: Laparotomy Thoracotomy Sternotomy Extremity Neck Mangled extremity/traumatic amputation Other skin/soft tissue Extraperitoneal pelvic packing None Missing
Angiography for hemorrhage control	Indicate first type of angiography to control hemorrhage / number, percentage Options: None Angiography only Angiography with embolization only Angiography with stent

Hospital Event Variables (see NTDS for further definitions):

Acute respiratory distress syndrome	/ number, percentage Options: Yes No
Cardiac arrest with CPR	/ number, percentage Options: Yes No
Myocardial infarction	/ number, percentage Options: Yes No
Pulmonary embolism	/ number, percentage Options: Yes No
Severe sepsis	/ number, percentage Options: Yes No
Stroke/CVA	/ number, percentage Options: Yes No
Ventilator-associated pneumonia	/ number, percentage Options: Yes No

Outcome Variables:

Total ICU length of stay	Cumulative time spent in ICU (days, include partial days) / mean, standard deviation, median, range
Total ICU length of stay	Cumulative time spent on ventilator (days, include partial days) / mean, standard deviation, median, range

Hospital discharge disposition	/ number, percentage Options: Short-term general hospital as inpatient Intermediate care facility Home with home health Short-term general hospital as inpatient Left against medical advice Deceased Home or self-care (routine discharge) Skilled nursing facility (SNF) Hospice care Court/law enforcement Inpatient rehab or designated unit Long Term Care Hospital (LTCH) Psychiatric hospital or unit Other type of institution not previous defined