

## Appendix A. The Study Case Report Form

**ACT-TBI-CRF****Patient Assessment**

Patient ID: \_\_\_\_ - \_\_\_\_

**1. Patient Assessment**

<b>1. Eligibility Criteria</b>	<b>Yes</b>	<b>No</b>
1.1 Adults $\geq$ 18 years old	<input type="checkbox"/>	<input type="checkbox"/>
1.2 Severe head injury (GCS score $\leq$ 8 after initial resuscitation) with the activation of the trauma code on mechanical respiratory ventilation at the time of imaging	<input type="checkbox"/>	<input type="checkbox"/>
<b>2. Inclusion Criteria</b>		
Same criteria as eligibility		
<b>3. Exclusion Criteria</b>		
<b>4. No known GCS after initial resuscitation</b>		
4.1 Patients with contraindications to CT-perfusion		
4.1.1 Pregnancy	<input type="checkbox"/>	<input type="checkbox"/>
4.1.2 Contrast allergy	<input type="checkbox"/>	<input type="checkbox"/>
4.1.3 Clinician refuses because of kidney injury	<input type="checkbox"/>	<input type="checkbox"/>
4.1.4 Hemodynamic instability that prevents safe transport to the CT-scan	<input type="checkbox"/>	<input type="checkbox"/>

Version Date: March 4, 2021

**ACT-TBI-CRF****Consent**

Patient ID: \_\_\_\_ - \_\_\_\_

**2. Consent**

1. Date/time consent was obtained (DD/MMM/YYYY) (hh:mm)	____ / ____ / 20____ : ____ (24hr)
2. Who provided consent?	<input type="checkbox"/> Substitute Decision Maker <input type="checkbox"/> Father <input type="checkbox"/> Mother <input type="checkbox"/> Brother <input type="checkbox"/> Sister <input type="checkbox"/> Spouse or partner <input type="checkbox"/> Daughter <input type="checkbox"/> Son <input type="checkbox"/> Other (specify): _____

Version Date: March 4, 2021

**ACT-TBI-CRF****Brain CT-Perfusion**

Patient ID: \_\_\_\_ - \_\_\_\_

**3. Brain CT-Perfusion**

1. CT Brain Perfusion Data		
1.1 Date/time patient left ED to perform CT: (DD/MMM/YYYY hh:mm)	____ / ____ / 20____ : ____	
1.2 Time CT performed: (hh:mm)	____ : ____ (24hr)	
1.3 Time patient returned to ED after performing CT: (hh:mm)	____ : ____ (24hr)	
1.4 Contrast media injected (non-ionic iodinated):	<input type="checkbox"/> 40 mL <input type="checkbox"/> Other, specify: _____ mL	
1.5 Type of contrast:	<input type="checkbox"/> Isovue 370 <input type="checkbox"/> Omnipaque 300 <input type="checkbox"/> Omnipaque 350 <input type="checkbox"/> Ultravist (iopromide) 370 <input type="checkbox"/> Visipaque 320 <input type="checkbox"/> Other (specify): _____	
1.6 CTP-related events experienced by patient (check all relevant events):		
<b><u>Events marked by an * must be reported to coordinating center within 24h:</u></b> <b><u>Study coordinator: Sudharsana Rao Ande, Tel 204 789 3996</u></b> <b><u>or</u></b> <b><u>Study PI: Dr Jai Shankar, tel 431-373-4164</u></b>		
Event	Time of occurrence	Requiring Treatment
<input type="checkbox"/> Hypertension (more than 180 mmHg systolic for 2 minutes)	____ : ____ (24h)	<input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, please specify: _____ _____
<input type="checkbox"/> Hypotension (less than 60 mmHg mean arterial pressure for 2 minutes)	____ : ____ (24h)	<input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, please specify: _____ _____
<input type="checkbox"/> New desaturation less than 88% for more than 1 minute	____ : ____ (24h)	<input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, please specify: _____ _____
<input type="checkbox"/> <b>Accidental extubation*</b>	____ : ____ (24h)	<input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, please specify: _____ _____

Version Date: March 4, 2021

**ACT-TBI-CRF****Brain CT-Perfusion**

Patient ID: \_\_\_\_ - \_\_\_\_

<input type="checkbox"/> New catheter dysfunction (obstruction, removal)	____ : ____ (24h)	<input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, please specify: _____ _____
<input type="checkbox"/> <b>Code blue (or equivalent)*</b>	____ : ____ (24h)	<input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, please specify: _____ _____
<input type="checkbox"/> Other (specify): _____	____ : ____ (24h)	<input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, please specify: _____ _____
<b>1.7 Iodine injection related events:</b>		
<input type="checkbox"/> Minor adverse events (self-limiting, non-progressive):  New: limited urticaria, limited cutaneous edema, rhinorrhea, conjunctivitis	____ : ____ (24h)	<input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, please specify: _____ _____
<input type="checkbox"/> Moderate adverse events (often require management):  New: diffuse urticaria, facial edema, bronchospasm, mild hypoxia	____ : ____ (24h)	<input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, please specify: _____ _____
<input type="checkbox"/> <b>Severe reactions (often require intervention): *</b>  New: diffuse erythema/edema with hypotension, laryngeal edema with stridor and/or hypoxia, wheezing/bronchospasm, significant hypoxia, anaphylactic shock (hypotension + tachycardia)	____ : ____ (24h)	<input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, please specify: _____ _____
<input type="checkbox"/> No CTP or iodine injection related events		
<b>2.</b>		
2.1		
<b>Notes:</b> _____ _____ _____		

Version Date: March 4, 2021

**ACT-TBI-CRF****Baseline**

Patient ID: \_\_\_\_ - \_\_\_\_

**4. Baseline**

1. Date of birth (MMM/YYYY)	____ / ____
2. Date of injury (and approximate time) (DD/MMM/YYYY) (hh:mm)	____ / ____ / 20 ____ : ____ (24hr)
3. Sex at birth	<input type="checkbox"/> Male <input type="checkbox"/> Female
4. Race	<input type="checkbox"/> Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> Caucasian <input type="checkbox"/> First Nations <input type="checkbox"/> Unknown <input type="checkbox"/> Other, specify _____
5. Mode of trauma	<input type="checkbox"/> Traumatic Brain Injury (TBI) <ul style="list-style-type: none"> <li><input type="checkbox"/> Open TBI with intracranial hemorrhage</li> <li><input type="checkbox"/> Close TBI with intracranial hemorrhage</li> <li><input type="checkbox"/> Open TBI without intracranial hemorrhage</li> <li><input type="checkbox"/> Close TBI without intracranial hemorrhage</li> <li><input type="checkbox"/> Motor Vehicle injury      <input type="checkbox"/> Physical assault</li> <li><input type="checkbox"/> Gun-Shot injury              <input type="checkbox"/> Stabbing</li> <li><input type="checkbox"/> Electrocutation              <input type="checkbox"/> Asphyxiation (choking or suffocation)</li> <li><input type="checkbox"/> Other, specify: _____</li> </ul>

Version Date: March 4, 2021

**ACT-TBI-CRF****Baseline**

Patient ID: \_\_\_\_ - \_\_\_\_

6. Injury Severity Score Head and Neck	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 (1-Minor; 2-Moderate; 3-Serious; 4-Severe; 5-Critical; 6 -Unsurvivable)
7. Injury Severity Score Face	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 (1-Minor; 2-Moderate; 3-Serious; 4-Severe; 5-Critical; 6 -Unsurvivable)
8. Injury Severity Score Chest	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 (1-Minor; 2-Moderate; 3-Serious; 4-Severe; 5-Critical; 6 -Unsurvivable)
9. Injury Severity Score Abdomen	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 (1-Minor; 2-Moderate; 3-Serious; 4-Severe; 5-Critical; 6 -Unsurvivable)
10. Injury Severity Score Extremity	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 (1-Minor; 2-Moderate; 3-Serious; 4-Severe; 5-Critical; 6 -Unsurvivable)
11. Injury Severity Score External	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 (1-Minor; 2-Moderate; 3-Serious; 4-Severe; 5-Critical; 6 -Unsurvivable)
12. Weight at ED admission	_____ Kg
13. Height	_____ cm

Version Date: March 4, 2021

**ACT-TBI-CRF****Baseline**

Patient ID: \_\_\_\_ - \_\_\_\_

14. Comorbidities	<input type="checkbox"/> Hypertension treated with medication <input type="checkbox"/> Hypertension not treated or not known to be treated with medication <input type="checkbox"/> Diabetes <input type="checkbox"/> Coronary artery disease <input type="checkbox"/> Peripheral vascular disease <input type="checkbox"/> Previous stroke <input type="checkbox"/> Active smoking <input type="checkbox"/> Smoking history (known past history) <input type="checkbox"/> Chronic renal failure with dialysis <input type="checkbox"/> Chronic renal failure without dialysis <input type="checkbox"/> Liver disease <input type="checkbox"/> Other, specify _____ <input type="checkbox"/> None <input type="checkbox"/> None specified/unknown
-------------------	--

15. Admission information	
<u>Previous hospital (if patient transferred from another hospital):</u>	
15.1. First hospital ED admission date/time (DD/MMM/YYYY hh:mm)	____ / ____ / 20 ____ : ____ (24hr) <input type="checkbox"/> Not applicable
15.2. First hospital discharge date/time (DD/MMM/YYYY hh:mm)	____ / ____ / 20 ____ : ____ (24hr) <input type="checkbox"/> Not applicable
<u>Current hospital :</u>	
15.3. ED admission date/time (if patient not transferred from another hospital) (DD/MMM/YYYY hh:mm)	____ / ____ / 20 ____ : ____ (24hr) <input type="checkbox"/> Not applicable
15.4. ICU admission date/time (DD/MMM/YYYY hh:mm)	____ / ____ / 20 ____ : ____ (24hr)

Version Date: March 4, 2021

**ACT-TBI-CRF****Baseline**

Patient ID: \_\_\_\_ - \_\_\_\_

16. Record documented GCS at each of the following stage:		
16.1. On scene	Eye	<input type="checkbox"/> Not available
	Verbal	<input type="checkbox"/> Not available
	Motor	<input type="checkbox"/> Not available
	Total	<input type="checkbox"/> Not available
16.2. ED GCS (From first hospital: previous or current hospital)	Eye	<input type="checkbox"/> Not available
	Verbal	<input type="checkbox"/> Not available
	Motor	<input type="checkbox"/> Not available
	Total	<input type="checkbox"/> Not available
16.3. ICU GCS (From previous hospital if patient transferred)	Eye	<input type="checkbox"/> Not available <input type="checkbox"/> Not applicable
	Verbal	<input type="checkbox"/> Not available <input type="checkbox"/> Not applicable
	Motor	<input type="checkbox"/> Not available <input type="checkbox"/> Not applicable
	Total	<input type="checkbox"/> Not available <input type="checkbox"/> Not applicable
16.4. ICU admission of current hospital (first available)	Eye	<input type="checkbox"/> Not available
	Verbal	<input type="checkbox"/> Not available
	Motor	<input type="checkbox"/> Not available
	Total	<input type="checkbox"/> Not available

17. If patient transferred from another hospital: <u>Last</u> laboratory data measures available from previous hospital (specify value and date of test for each parameter)			<input type="checkbox"/> Not applicable
Biochemistry			
17.1. Blood glucose (mmol/L):		____ / ____ / 20	<input type="checkbox"/> Not available
17.2. Hemoglobin (g/L):		<input type="checkbox"/> Same date as above <u>OR</u> ____ / ____ / 20	<input type="checkbox"/> Not available
17.3. Na+ (mmol/L):		<input type="checkbox"/> Same date as above <u>OR</u> ____ / ____ / 20	<input type="checkbox"/> Not available
17.4. K+ (mmol/L):		<input type="checkbox"/> Same date as above <u>OR</u> ____ / ____ / 20	<input type="checkbox"/> Not available
17.5. Creatinine (µmol/L):		<input type="checkbox"/> Same date as above <u>OR</u> ____ / ____ / 20	<input type="checkbox"/> Not available
17.6. BUN (mmol/L):		<input type="checkbox"/> Same date as above <u>OR</u> ____ / ____ / 20	<input type="checkbox"/> Not available

Version Date: March 4, 2021



**ACT-TBI-CRF****Baseline**

Patient ID: \_\_\_\_\_ - \_\_\_\_\_

Blood Gases (Specify method)	<input type="checkbox"/> Arterial <input type="checkbox"/> Capillary <input type="checkbox"/> Venous ____ / ____ / 20 ____ Use same method and gas for the following questions.		<input type="checkbox"/> Not available
17.7. pH:	_____		
17.8. HCO <sub>3</sub> (mmol/L):	_____		
17.9. PCO <sub>2</sub> (mmHg):	_____		
17.10. PaO <sub>2</sub> (mmHg):	_____		
17.11. FiO <sub>2</sub> (%):	_____		
<b>Vital Signs</b>			
17.12. Systolic BP (mmHg):	_____	<input type="checkbox"/> Same date as above <u>OR</u> ____ / ____ / 20 ____	<input type="checkbox"/> Not available
17.13. Diastolic BP (mmHg):	_____	<input type="checkbox"/> Same date as above <u>OR</u> ____ / ____ / 20 ____	<input type="checkbox"/> Not available
17.14. MAP (mmHg):	_____	<input type="checkbox"/> Same date as above <u>OR</u> ____ / ____ / 20 ____	<input type="checkbox"/> Not available
17.15. Heart Rate (bpm):	_____	<input type="checkbox"/> Same date as above <u>OR</u> ____ / ____ / 20 ____	<input type="checkbox"/> Not available
17.16. Body Temperature (°C):	_____	<input type="checkbox"/> Same date as above <u>OR</u> ____ / ____ / 20 ____ <input type="checkbox"/> Rectal <input type="checkbox"/> Oral <input type="checkbox"/> Axillary <input type="checkbox"/> Not specified <input type="checkbox"/> Other, specify _____	<input type="checkbox"/> Not available
17.17. Total Fluid Balance (mL)	<input type="checkbox"/> + <input type="checkbox"/> - _____	<input type="checkbox"/> Same date as above <u>OR</u> ____ / ____ / 20 ____	<input type="checkbox"/> Not available

<b>18. First available laboratory data in ED (current hospital)</b> Specify value and date of test for each parameter.			
<b>Biochemistry</b>			
18.1. Blood glucose (mmol/L):	_____	<input type="checkbox"/> Same date as above <u>OR</u> ____ / ____ / 20 ____	<input type="checkbox"/> NA
18.2. Hemoglobin (g/L):	_____	<input type="checkbox"/> Same date as above <u>OR</u> ____ / ____ / 20 ____	<input type="checkbox"/> NA
18.3. Na <sup>+</sup> (mmol/L):	_____	<input type="checkbox"/> Same date as above <u>OR</u> ____ / ____ / 20 ____	<input type="checkbox"/> NA
18.4. K <sup>+</sup> (mmol/L):	_____	<input type="checkbox"/> Same date as above <u>OR</u> ____ / ____ / 20 ____	<input type="checkbox"/> NA
18.5. Creatinine (µmol/L):	_____	<input type="checkbox"/> Same date as above <u>OR</u> ____ / ____ / 20 ____	<input type="checkbox"/> NA
18.6. BUN (mmol/L):	_____	<input type="checkbox"/> Same date as above <u>OR</u> ____ / ____ / 20 ____	<input type="checkbox"/> NA
Blood Gases (Specify method)	<input type="checkbox"/> Arterial <input type="checkbox"/> Capillary <input type="checkbox"/> Venous ____ / ____ / 20 ____ Use same method and gas for the following questions.		<input type="checkbox"/> NA
18.7. pH:	_____		

Version Date: March 4, 2021

**ACT-TBI-CRF****Baseline**

Patient ID: \_\_\_\_ - \_\_\_\_

18.8. HCO <sub>3</sub> (mmol/L):			
18.9. PCO <sub>2</sub> (mmHg):			
18.10. PaO <sub>2</sub> (mmHg):			
18.11. FiO <sub>2</sub> (%):			
<b>Vital Signs</b>			
18.12. Systolic BP (mmHg):		<input type="checkbox"/> Same date as above <u>OR</u> / / 20	<input type="checkbox"/> NA
18.13. Diastolic BP (mmHg):		<input type="checkbox"/> Same date as above <u>OR</u> / / 20	<input type="checkbox"/> NA
18.14. MAP (mmHg):		<input type="checkbox"/> Same date as above <u>OR</u> / / 20	<input type="checkbox"/> NA
18.15. Heart Rate (bpm):		<input type="checkbox"/> Same date as above <u>OR</u> / / 20	<input type="checkbox"/> NA
18.16. Body Temperature (°C):		<input type="checkbox"/> Same date as above <u>OR</u> / / 20	<input type="checkbox"/> NA
<input type="checkbox"/> Rectal <input type="checkbox"/> Oral <input type="checkbox"/> Axillary <input type="checkbox"/> Not specified <input type="checkbox"/> Other, specify			

**Surgery /Interventions**

19. Date of Operations/Interventions (DD/MMM/YYYY) (hh:mm)	____ / ____ / 20 ____ : ____ (24hr)
20. Operation/Intervention List date and time with each.	

Version Date: March 4, 2021

**ACT-TBI-CRF****Daily Data Collection**

Patient ID: \_\_\_\_ - \_\_\_\_

**5. Daily Data Collection**

Clinical data for 7 days after inclusion into the study						
<input type="checkbox"/> Day 1 (Enrollment Date)	<input type="checkbox"/> Day 2	<input type="checkbox"/> Day 3	<input type="checkbox"/> Day 4	<input type="checkbox"/> Day 5	<input type="checkbox"/> Day 6	<input type="checkbox"/> Day 7
1. Date (DD/MMM/YYYY)			____ / ____ / 20__			
2. GCS*			<b>Worst value of the day</b>	<b>Best value of the day</b>		
			<input type="checkbox"/> with sedation <input type="checkbox"/> without sedation	<input type="checkbox"/> with sedation <input type="checkbox"/> without sedation		
• Eye			____	____		
• Verbal			1 (T)	1 (T)		
• Motor			____	____		
• Total GCS & time of assessment (hh:mm)			@ ____ : ____	@ ____ : ____		
<b>Complete the questions 2.1 to 2.6 if the total GCS best value is more than 3:</b>			<b>Cranial nerve territory response</b>	<b>Peripheral nerve territory response</b>		
<input type="checkbox"/> Not applicable						
2.1. Painful stimulation above clavicles			<input type="checkbox"/> Absent <input type="checkbox"/> Present <input type="checkbox"/> Not available	<input type="checkbox"/> Absent <input type="checkbox"/> Present <input type="checkbox"/> Not available		
2.2. If presence of a peripheral response, is that response a spinal reflex?			<input type="checkbox"/> Yes, it is a spinal reflex <input type="checkbox"/> Both spinal and upper motoneuron mediated reflexes present <input type="checkbox"/> No, it is an upper motoneuron mediated reflex <input type="checkbox"/> Unsure <input type="checkbox"/> Not available			
2.3. Pupillary response to light		Right	<input type="checkbox"/> Absent <input type="checkbox"/> Present <input type="checkbox"/> Not available			
		Left	<input type="checkbox"/> Absent <input type="checkbox"/> Present <input type="checkbox"/> Not available			
2.4. Corneal response		Right	<input type="checkbox"/> Absent <input type="checkbox"/> Present <input type="checkbox"/> Not available			
		Left	<input type="checkbox"/> Absent <input type="checkbox"/> Present <input type="checkbox"/> Not available			
2.5. Cough reflex			<input type="checkbox"/> Absent <input type="checkbox"/> Present <input type="checkbox"/> Not available			
2.6. Pharyngeal (gag) reflex			<input type="checkbox"/> Absent <input type="checkbox"/> Present <input type="checkbox"/> Not available			

<b>*Glasgow Coma Scale (GCS)</b>		
<b>Eye GCS</b>	<b>Verbal GCS</b>	<b>Motor GCS</b>
4 – Spontaneously eye opening 3 – Eye opening in response to verbal command 2 – Eye opening in response to pain 1 – No response	5 – Orientated 4 – Confused conversation 3 – Words (inappropriate) 2 – Sounds (incomprehensible) 1 – No response	6 – Obeys (moves according to) verbal commands 5 – Localizes pain 4 – Flexion-withdrawal 3 – Flexion-abnormal/decorticate rigidity 2 – Extension/decerebrate rigidity 1 – No response

Version Date: March 4, 2021

**ACT-TBI-CRF****Daily Data Collection**

Patient ID: \_\_\_\_ - \_\_\_\_

3. Biochemistry						
<input type="checkbox"/> Day 1 (Enrollment Date)	<input type="checkbox"/> Day 2	<input type="checkbox"/> Day 3	<input type="checkbox"/> Day 4	<input type="checkbox"/> Day 5	<input type="checkbox"/> Day 6	<input type="checkbox"/> Day 7
3.1. Blood glucose (mmol/L):			Lowest: _____	Highest: _____		<input type="checkbox"/> NA
3.2. Hemoglobin (g/L):			Lowest: _____	Highest: _____		<input type="checkbox"/> NA
3.3. Platelets (10 <sup>9</sup> /L):			Lowest: _____	Highest: _____		<input type="checkbox"/> NA
3.4. Na <sup>+</sup> (mmol/L):			Lowest: _____	Highest: _____		<input type="checkbox"/> NA
3.5. K <sup>+</sup> (mmol/L):			Lowest: _____	Highest: _____		<input type="checkbox"/> NA
3.6. Creatinine (µmol/L):			Lowest: _____	Highest: _____		<input type="checkbox"/> NA
3.7. BUN (mmol/L):			Lowest: _____	Highest: _____		<input type="checkbox"/> NA
3.8. Albumin (g/L):			Lowest: _____		<input type="checkbox"/> NA	
3.9. Total bilirubin (µmol/L):			Highest: _____		<input type="checkbox"/> NA	
3.10. AST (U/L):			Highest: _____		<input type="checkbox"/> NA	
3.11. ALT (U/L):			Highest: _____		<input type="checkbox"/> NA	
3.12. Has the patient any of the following Acute Kidney Injury criteria: <ul style="list-style-type: none"> <li>• Increase in serum creatinine by <math>\geq 26.5</math> mol/l within 48 hours;</li> <li>• Increase in serum creatinine to <math>\geq 1.5</math> times baseline, which is known or presumed to have occurred within the prior 7 days;</li> <li>• Urine volume <math>&lt; 0.5</math> ml/kg/h for 6 hours.</li> </ul>			<input type="checkbox"/> Yes <input type="checkbox"/> No			
3.13. What is the patient KDIGO Acute Kidney Injury Stage?			<input type="checkbox"/> No Acute Kidney Injury			
			<input type="checkbox"/> Stage 1	<ul style="list-style-type: none"> <li>• Serum creatinine 1.5-1.9 times baseline OR <math>\geq 26.5</math> µmol/l increase</li> <li>• Urine output of <math>&lt; 0.5</math> ml/kg/h for 6–12 hours</li> </ul>		
			<input type="checkbox"/> Stage 2	<ul style="list-style-type: none"> <li>• Serum creatinine 2.0-22.9 times baseline</li> <li>• Urine output of <math>&lt; 0.5</math> ml/kg/h for <math>\geq 12</math> hours</li> </ul>		
			<input type="checkbox"/> Stage 3	<ul style="list-style-type: none"> <li>• Serum creatinine 3.0-22.9 times baseline OR Increase in serum creatinine to <math>\geq 353.6</math> µmol/l OR Initiation of renal replacement therapy</li> <li>• Urine output of <math>&lt; 0.3</math> ml/kg/h for <math>\geq 24</math> hours OR Anuria for <math>\geq 12</math> hours</li> </ul>		

Version Date: March 4, 2021

**ACT-TBI-CRF****Daily Data Collection**

Patient ID: \_\_\_\_ - \_\_\_\_

4. Blood Gases						
<input type="checkbox"/> Day 1 (Enrollment Date)	<input type="checkbox"/> Day 2	<input type="checkbox"/> Day 3	<input type="checkbox"/> Day 4	<input type="checkbox"/> Day 5	<input type="checkbox"/> Day 6	<input type="checkbox"/> Day 7
Blood Gas based on lowest pH (Specify method)				<input type="checkbox"/> Arterial <input type="checkbox"/> Capillary <input type="checkbox"/> Venous Use same gas for following questions.		
4.1. pH:				_____	<input type="checkbox"/> NA	
4.2. HCO <sub>3</sub> (mmol/L):				_____	<input type="checkbox"/> NA	
4.3. PCO <sub>2</sub> (mmHg):				_____	<input type="checkbox"/> NA	
4.4. PaO <sub>2</sub> (mmHg):				_____	<input type="checkbox"/> NA	
4.5. FiO <sub>2</sub> (%):				_____	<input type="checkbox"/> NA	
Blood Gas based on highest pH (Specify method)				<input type="checkbox"/> Arterial <input type="checkbox"/> Capillary <input type="checkbox"/> Venous Use same gas for following questions.		
4.6. pH:				_____	<input type="checkbox"/> NA	
4.7. HCO <sub>3</sub> (mmol/L):				_____	<input type="checkbox"/> NA	
4.8. PCO <sub>2</sub> (mmHg):				_____	<input type="checkbox"/> NA	
4.9. PaO <sub>2</sub> (mmHg):				_____	<input type="checkbox"/> NA	
4.10. FiO <sub>2</sub> (%):				_____	<input type="checkbox"/> NA	

Version Date: March 4, 2021

**ACT-TBI-CRF****Daily Data Collection**

Patient ID: \_\_\_\_ - \_\_\_\_

5. Vital Signs						
<input type="checkbox"/> Day 1 (Enrollment Date)	<input type="checkbox"/> Day 2	<input type="checkbox"/> Day 3	<input type="checkbox"/> Day 4	<input type="checkbox"/> Day 5	<input type="checkbox"/> Day 6	<input type="checkbox"/> Day 7
5.1. Systolic BP (mmHg):			Lowest: _____	Highest: _____	<input type="checkbox"/> NA	
5.2. Diastolic BP (mmHg):			Lowest: _____	Highest: _____	<input type="checkbox"/> NA	
5.3. MAP (mmHg):			Lowest: _____	Highest: _____	<input type="checkbox"/> NA	
5.4. Heart Rate (bpm):			Lowest: _____	Highest: _____	<input type="checkbox"/> NA	
5.5. Body Temperature (°C):			Lowest: _____ Highest: _____		<input type="checkbox"/> NA	
			<input type="checkbox"/> Rectal <input type="checkbox"/> Oral <input type="checkbox"/> Axillary <input type="checkbox"/> Not specified <input type="checkbox"/> Other, specify _____			
5.6. 24h Fluid Balance (mL):			<input type="checkbox"/> + <input type="checkbox"/> -	_____	<input type="checkbox"/> NA	

Version Date: March 4, 2021

**ACT-TBI-CRF****Daily Data Collection**

Patient ID: \_\_\_\_ - \_\_\_\_

1. Record all sedatives, analgesics, anti-psychotics, barbiturates & vasopressors/inotropes received **from day of ED arrival / enrolment** .

Sedatives - Bolus				□ No data to report	
Please choose letter from table below	Date Administered	Time Administered (hh:mm)	Route	Dose	Unit
□ _____	___/___/20___	___:___	□ PO □ IV □ SC	_____	□ mg □ µg
□ _____	___/___/20___	___:___	□ PO □ IV □ SC	_____	□ mg □ µg
□ _____	___/___/20___	___:___	□ PO □ IV □ SC	_____	□ mg □ µg
□ _____	___/___/20___	___:___	□ PO □ IV □ SC	_____	□ mg □ µg
□ _____*	___/___/20___	___:___	□ PO □ IV □ SC	_____	□ mg □ µg

Sedatives – Continuous Infusion				□ No data to report	
Please choose letter from table below	Date & Time Started	Date & Time Ended	Rate	Unit	
□ _____	___/___/20___ :___:___	___/___/20___ :___:___	_____	If mL/h or mL/min, provide concentration: _____	
□ _____	___/___/20___ :___:___	___/___/20___ :___:___	_____	If mL/h or mL/min, provide concentration: _____	
□ _____	___/___/20___ :___:___	___/___/20___ :___:___	_____	If mL/h or mL/min, provide concentration: _____	
□ _____	___/___/20___ :___:___	___/___/20___ :___:___	_____	If mL/h or mL/min, provide concentration: _____	
□ _____*	___/___/20___ :___:___	___/___/20___ :___:___	_____	If mL/h or mL/min, provide concentration: _____	

Table: Options for Sedatives			
<b>A:</b> Propofol (Diprivan)	<b>C:</b> Lorazepam (Ativan)	<b>G:</b> Clonazepam (Rivotril)	<b>I:</b> Dexmedetomidine (Precedex)
<b>B:</b> Midazolam (Versed)	<b>D:</b> Diazepam (Valium)	<b>H:</b> Ketamine (Ketalor)	<b>J:</b> Other (specify)

\***Note:** If more bolus & continuous infusion were used, please use a supplementary form, and specify the number of the form: #\_\_.

Version Date: March 4, 2021

## ACT-TBI-CRF

## Daily Data Collection

Patient ID: \_\_\_\_ - \_\_\_\_

Analgesics - Bolus				□ No data to report	
Please choose letter from table below	Date Administered	Time Administered (hh:mm)	Route	Dose	Unit
□ _____	___/___/20__	___:___	□ PO □ IV □ SC	_____	□ mg □ µg
□ _____	___/___/20__	___:___	□ PO □ IV □ SC	_____	□ mg □ µg
□ _____	___/___/20__	___:___	□ PO □ IV □ SC	_____	□ mg □ µg
□ _____	___/___/20__	___:___	□ PO □ IV □ SC	_____	□ mg □ µg
□ _____*	___/___/20__	___:___	□ PO □ IV □ SC	_____	□ mg □ µg

Analgesics – Continuous Infusion				□ No data to report	
Please choose letter from table below	Date & Time Started	Date & Time Ended	Rate	Unit	
□ _____	___/___/20__ ___:___	___/___/20__ ___:___	_____	If mL/h or mL/min, provide concentration: _____	
□ _____	___/___/20__ ___:___	___/___/20__ ___:___	_____	If mL/h or mL/min, provide concentration: _____	
□ _____	___/___/20__ ___:___	___/___/20__ ___:___	_____	If mL/h or mL/min, provide concentration: _____	
□ _____	___/___/20__ ___:___	___/___/20__ ___:___	_____	If mL/h or mL/min, provide concentration: _____	
□ _____*	___/___/20__ ___:___	___/___/20__ ___:___	_____	If mL/h or mL/min, provide concentration: _____	

Table: Options for Analgesics		
<b>A:</b> Morphine	<b>C:</b> Remifentanyl (Ultiva)	<b>G:</b> Hydromorphone
<b>B:</b> Fentanyl	<b>D:</b> Sufentanil (Sufenta)	<b>H:</b> Other (specify)

\***Note:** If more bolus & continuous infusion were used, please use a supplementary form, and specify the number of the form: # \_\_\_\_.

Version Date: March 4, 2021



**ACT-TBI-CRF****Daily Data Collection**

Patient ID: \_\_\_ - \_\_\_

Anti-psychotics - Bolus				□ No data to report	
Please choose letter from table below	Date Administered	Time Administered (hh:mm)	Route	Dose	Unit
□ _____	___/___/20__	___:___	□ PO □ IV □ SC	_____	□ mg □ µg
□ _____	___/___/20__	___:___	□ PO □ IV □ SC	_____	□ mg □ µg
□ _____	___/___/20__	___:___	□ PO □ IV □ SC	_____	□ mg □ µg
□ _____	___/___/20__	___:___	□ PO □ IV □ SC	_____	□ mg □ µg
□ _____*	___/___/20__	___:___	□ PO □ IV □ SC	_____	□ mg □ µg

Anti-psychotics – Continuous Infusion				□ No data to report	
Please choose letter from table below	Date & Time Started	Date & Time Ended	Rate	Unit	
□ _____	___/___/20__ ___:___	___/___/20__ ___:___	_____	If mL/h or mL/min, provide concentration: _____	
□ _____	___/___/20__ ___:___	___/___/20__ ___:___	_____	If mL/h or mL/min, provide concentration: _____	
□ _____	___/___/20__ ___:___	___/___/20__ ___:___	_____	If mL/h or mL/min, provide concentration: _____	
□ _____	___/___/20__ ___:___	___/___/20__ ___:___	_____	If mL/h or mL/min, provide concentration: _____	
□ _____*	___/___/20__ ___:___	___/___/20__ ___:___	_____	If mL/h or mL/min, provide concentration: _____	

Table: Options for Anti-psychotics		
<b>A:</b> Haloperidol (Haldol)	<b>C:</b> Quetiapine (Seroquel)	<b>G:</b> Other (specify)
<b>B:</b> Risperdone (Risperdal)	<b>D:</b> Olanzapine (Zyprexa)	

**\*Note:** If more bolus & continuous infusion were used, please use a supplementary form, and specify the number of the form: # \_\_\_

Version Date: March 4, 2021

**ACT-TBI-CRF****Daily Data Collection**

Patient ID: \_\_\_\_ - \_\_\_\_

Barbiturates- Bolus				□ No data to report	
Please choose letter from table below	Date Administered	Time Administered (hh:mm)	Route	Dose	Unit
□ _____	___/___/20__	___:___	□ PO □ IV □ SC	_____	□ mg □ µg
□ _____	___/___/20__	___:___	□ PO □ IV □ SC	_____	□ mg □ µg
□ _____	___/___/20__	___:___	□ PO □ IV □ SC	_____	□ mg □ µg
□ _____	___/___/20__	___:___	□ PO □ IV □ SC	_____	□ mg □ µg
□ _____*	___/___/20__	___:___	□ PO □ IV □ SC	_____	□ mg □ µg

Barbiturates – Continuous Infusion				□ No data to report	
Please choose letter from table below	Date & Time Started	Date & Time Ended	Rate	Unit	
□ _____	___/___/20__ ___:___	___/___/20__ ___:___	_____	If mL/h or mL/min, provide concentration: _____	
□ _____	___/___/20__ ___:___	___/___/20__ ___:___	_____	If mL/h or mL/min, provide concentration: _____	
□ _____	___/___/20__ ___:___	___/___/20__ ___:___	_____	If mL/h or mL/min, provide concentration: _____	
□ _____	___/___/20__ ___:___	___/___/20__ ___:___	_____	If mL/h or mL/min, provide concentration: _____	
□ _____*	___/___/20__ ___:___	___/___/20__ ___:___	_____	If mL/h or mL/min, provide concentration: _____	

**Table: Options for Barbiturates**

<b>A:</b> Pentobarbital (Nembutal)	<b>C:</b> Thiopental (Pentothal)
<b>B:</b> Phenobarbital (Luminal)	<b>D:</b> Other (specify)

**\*Note:** If more bolus & continuous infusion were used, please use a supplementary form, and specify the number of the form: # \_\_\_\_.

Version Date: March 4, 2021

**ACT-TBI-CRF****Daily Data Collection**

Patient ID: \_\_\_\_ - \_\_\_\_

Vasopressors/Inotropes - Bolus				□ No data to report	
Please choose letter from table below	Date Administered	Time Administered (hh:mm)	Route	Dose	Unit
□ _____	___/___/20__	__:__:__	□ PO □ IV □ SC	_____	□ mg □ µg
□ _____	___/___/20__	__:__:__	□ PO □ IV □ SC	_____	□ mg □ µg
□ _____	___/___/20__	__:__:__	□ PO □ IV □ SC	_____	□ mg □ µg
□ _____	___/___/20__	__:__:__	□ PO □ IV □ SC	_____	□ mg □ µg
□ _____*	___/___/20__	__:__:__	□ PO □ IV □ SC	_____	□ mg □ µg

Vasopressors/Inotropes – Continuous Infusion			□ No data to report	
Please choose letter from table below	Date & Time Started	Date & Time Ended	Maximum Rate (Unit)	Total Dose (Unit)
□ _____	___/___/20__ :__:	___/___/20__ :__:	_____ (_____)° °If mL/h or mL/min, provide concentration: _____	(_____)
□ _____	___/___/20__ :__:	___/___/20__ :__:	_____ (_____)° °If mL/h or mL/min, provide concentration: _____	(_____)
□ _____	___/___/20__ :__:	___/___/20__ :__:	_____ (_____)° °If mL/h or mL/min, provide concentration: _____	(_____)
□ _____	___/___/20__ :__:	___/___/20__ :__:	_____ (_____)° °If mL/h or mL/min, provide concentration: _____	(_____)
□ _____*	___/___/20__ :__:	___/___/20__ :__:	_____ (_____)° °If mL/h or mL/min, provide concentration: _____	(_____)

Table: Options for Vasopressors/Inotropes			
<b>A:</b> Vasopressin	<b>C:</b> Phenylephrine	<b>G:</b> Dopamine	<b>I:</b> Milrinone
<b>B:</b> Norepinephrine	<b>D:</b> Epinephrine	<b>H:</b> Dobutamine	<b>J:</b> Other (specify)

\***Note:** If more perfusions were used, please use a supplementary form, and specify the number of the form: #\_\_..

Version Date: March 4, 2021

**ACT-TBI-CRF****Daily Data Collection**

Patient ID: \_\_\_\_ - \_\_\_\_

Other Medications - Bolus				□ No data to report	
Please choose letter from table below	Date Administered	Time Administered (hh:mm)	Route	Dose	Unit
□ _____	___/___/20__	__:__	□ PO □ IV □ SC	_____	□ mg □ µg
□ _____	___/___/20__	__:__	□ PO □ IV □ SC	_____	□ mg □ µg
□ _____	___/___/20__	__:__	□ PO □ IV □ SC	_____	□ mg □ µg
□ _____	___/___/20__	__:__	□ PO □ IV □ SC	_____	□ mg □ µg
□ _____*	___/___/20__	__:__	□ PO □ IV □ SC	_____	□ mg □ µg
Other Medications – Continuous Infusion				□ No data to report	
Please choose letter from table below	Date & Time Started	Date & Time Ended	Maximum Rate (Unit)	Total Dose (Unit)	
□ _____	___/___/20__ :__	___/___/20__ :__	_____ (_____)° °If mL/h or mL/min, provide concentration: _____	(_____)	
□ _____	___/___/20__ :__	___/___/20__ :__	_____ (_____)° °If mL/h or mL/min, provide concentration: _____	(_____)	
□ _____	___/___/20__ :__	___/___/20__ :__	_____ (_____)° °If mL/h or mL/min, provide concentration: _____	(_____)	
□ _____	___/___/20__ :__	___/___/20__ :__	_____ (_____)° °If mL/h or mL/min, provide concentration: _____	(_____)	

Version Date: March 4, 2021

**ACT-TBI-CRF****Daily Data Collection**

Patient ID: \_\_\_\_ - \_\_\_\_

Cerebral Monitoring:  Not applicable

Type of monitoring/device	<input type="checkbox"/> Parenchymal intracranial pressure monitor (mm Hg)	<input type="checkbox"/> PbtO <sub>2</sub> monitor	<input type="checkbox"/> Cerebral oximetry monitoring (NIRS) (%)	<input type="checkbox"/> Intraventricular pressure monitor (mm Hg)	<input type="checkbox"/> Other (specify): _____
Date installed	___/___/20__	___/___/20__	___/___/20__	___/___/20__	___/___/20__
Date removed	___/___/20__	___/___/20__	___/___/20__	___/___/20__	___/___/20__
Record worst value of the day					
Day 1 (Day of study consent)	_____	_____	_____	_____	_____
Day 2	_____	_____	_____	_____	_____
Day 3	_____	_____	_____	_____	_____
Day 4	_____	_____	_____	_____	_____
Day 5	_____	_____	_____	_____	_____
Day 6	_____	_____	_____	_____	_____
Day 7	_____	_____	_____	_____	_____

<input type="checkbox"/> Cerebral dialysis	Date installed	___/___/20__		Date removed	___/___/20__	
	Glucose (mmol/L)	Lactate (mmol/L)	Pyruvate (μmol/L)	Glutamate (μmol/L)	Lactate/Pyruvate ratio	
Record worst value of the day						
Day 1	_____	_____	_____	_____	_____	
Day 2	_____	_____	_____	_____	_____	
Day 3	_____	_____	_____	_____	_____	
Day 4	_____	_____	_____	_____	_____	
Day 5	_____	_____	_____	_____	_____	
Day 6	_____	_____	_____	_____	_____	
Day 7	_____	_____	_____	_____	_____	

Version Date: March 4, 2021

**ACT-TBI-CRF****Outcome Measures**

Patient ID: \_\_\_\_ - \_\_\_\_

**6. Outcome Measures**

<b>1. Is patient alive at Hospital discharge?</b>	
<input type="checkbox"/> Yes, Patient alive (complete only the following questions if Yes)	
1.1. Date of ICU discharge	____ / ____ / 20 ____
1.2. Is patient still alive at <b>hospital discharge?</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, date of hospital discharge: ____ / ____ / 20 ____
1.3. Hospital discharge location	<input type="checkbox"/> Home <input type="checkbox"/> Palliative Care Facility <input type="checkbox"/> Other Hospital ICU <input type="checkbox"/> Long-term Care Facility <input type="checkbox"/> Rehabilitation Centre <input type="checkbox"/> Other (specify): _____
<input type="checkbox"/> No, Patient died (complete only the following questions if No)	
a. Type of death (specify date/time)	<input type="checkbox"/> Cardio-circulatory arrest ____ / ____ / 20 ____ : ____ <input type="checkbox"/> Neurological death ____ / ____ / 20 ____ : ____
b. Cause of death	
c. Withdrawal of life-sustaining therapies	<input type="checkbox"/> Yes <input type="checkbox"/> No
d. Was an approach made for organ donation?	<input type="checkbox"/> Yes <input type="checkbox"/> No, because (check all that apply): <input type="checkbox"/> Unexpected death <input type="checkbox"/> Physician refusal <input type="checkbox"/> Lack of time <input type="checkbox"/> Lack of resources <input type="checkbox"/> Other (specify): _____

Version Date: March 4, 2021

**ACT-TBI-CRF****Outcome Measures**

Patient ID: \_\_\_\_ - \_\_\_\_

2. The following questions apply only if there was an approach for organ donation	
e. Was positive consent for organ donation obtained?	<input type="checkbox"/> Yes <input type="checkbox"/> No
f. Who obtained consent?	<input type="checkbox"/> Attending physician <input type="checkbox"/> Resident <input type="checkbox"/> Organ donation specialist (MD) <input type="checkbox"/> Organ donation specialist (nurse) <input type="checkbox"/> Organ donation organization staff <input type="checkbox"/> Other (specify): _____
g. Who led the discussion?	<input type="checkbox"/> Attending physician <input type="checkbox"/> Resident <input type="checkbox"/> Organ donation specialist (MD) <input type="checkbox"/> Organ donation specialist (nurse) <input type="checkbox"/> Organ donation organization staff <input type="checkbox"/> Other (specify): _____
h. Who was present during the discussion? (check all that apply)	<input type="checkbox"/> Parent <input type="checkbox"/> Siblings <input type="checkbox"/> Spouse/partner <input type="checkbox"/> Friend <input type="checkbox"/> Other (specify): _____
i. At what moment the family was approached (specify date/time)?	____ / ____ / 20____ : ____ If neurological death: <input type="checkbox"/> Before neurological death diagnosis <input type="checkbox"/> After neurological death diagnosis
j. Who provided consent?	<input type="checkbox"/> Parents <input type="checkbox"/> Siblings <input type="checkbox"/> Spouse/partner <input type="checkbox"/> Other (specify): _____
k. Date/time consent was obtained (DD/MMM/YYYY) (hh:mm)	____ / ____ / 20____ : ____ (24 hr)
l. Did the patient donate at least one organ?	<input type="checkbox"/> Yes <input type="checkbox"/> No If no, specify why: _____

2. Was the patient co-enrolled in another study?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
Complete the following questions for every co-enrolled study :			
Study Name	Study Protocol Identifier	Study Principal Investigator	Patient Identification Number (in the co-enrolled study)
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Version Date: March 4, 2021

**ACT-TBI-CRF****Long-term Follow-Up**

Patient ID: \_\_\_\_ - \_\_\_\_

**7. Long-term Follow-up**

<b>6 months follow-up</b>	<input type="checkbox"/> Not done because patient died prior to the 6 months follow-up  If patient died between ICU discharge and 6 months follow-up, specify date/time & cause of death: ____ / ____ / 20 ____ : ____ _____ _____
---------------------------	---

<b>A. extended Glasgow Outcome Scale (GOSe)</b>	
Date of evaluation (DD/MMM/YYYY):	____ / ____ / ____
Respondent:	<input type="checkbox"/> Patient alone <input type="checkbox"/> Relative/friend/caretaker alone <input type="checkbox"/> Patient plus relative/friend/caretaker
<b>Consciousness</b>	
1. Is the person able to obey simple commands or say any words?	<input type="checkbox"/> Yes <input type="checkbox"/> No (VS)
<b>Independence at home</b>	
2a. Is the assistance of another person at home essential every day for some activities of daily living?	<input type="checkbox"/> Yes <input type="checkbox"/> No <b>If no: go to 3</b>
2b. Do you/your relative need frequent help of someone to be around at home most of time?	<input type="checkbox"/> Yes (lower SD) <input type="checkbox"/> No (upper SD)
2c. Were you/was your relative independent at home before the injury?	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Independence outside home</b>	
3a. Are you/Is your relative able to shop without assistance?	<input type="checkbox"/> Yes <input type="checkbox"/> No (upper SD)

Version Date: March 4, 2021



**ACT-TBI-CRF****Long-term Follow-Up**

Patient ID: \_\_\_\_ - \_\_\_\_

3b. Were you/was your relative able to shop without assistance before?	<input type="checkbox"/> Yes <input type="checkbox"/> No
4a. Were you/was your relative able to travel locally without assistance?	<input type="checkbox"/> Yes <input type="checkbox"/> No (upper SD)
4b. Were you/was your relative able to travel locally without assistance before the injury?	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Work</b>	
5a. Are you/Is your relative currently able to work (or look after others at home) to their previous capacity?	<input type="checkbox"/> Yes <b>If Yes: go to 6</b> <input type="checkbox"/> No
5b. How restricted are you/is your relative?	
a. Reduced work capacity?	<input type="checkbox"/> a. (upper MD)
b. Able to work only in a sheltered workshop or non-competitive job or currently unable to work?	<input type="checkbox"/> b. (lower MD)
5c. Does the level of restriction represent a change in respect to the pre-brain injury situation?	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Social and Leisure Activities</b>	
6a. Are you/is your relative able to resume regular social and leisure activities outside home?	<input type="checkbox"/> Yes <b>If Yes: go to 7</b> <input type="checkbox"/> No
6b. What is the extent of restriction on your/your relative social and leisure activities?	
a. Participate a bit less: at least half as often as before injury	<input type="checkbox"/> a. (lower GR)
b. Participate much less: less than half as often	<input type="checkbox"/> b. (upper MD)
c. Unable to participate: rarely, if ever, take part	<input type="checkbox"/> c. (lower MD)
6c. Does the extent of restriction in regular social and leisure activities outside home represent a change in respect or pre-brain injury?	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Family and Friendships</b>	
7a. Has there been family or friendship disruption due to psychological problems?	<input type="checkbox"/> Yes <input type="checkbox"/> No <b>If No: go to 8</b>

Version Date: March 4, 2021

**ACT-TBI-CRF****Long-term Follow-Up**

Patient ID: \_\_\_\_ - \_\_\_\_

7b. What has been the extent of disruption or strain?	
a. Occasional – less than weekly b. Frequent – once a week or more, but not tolerable c. Constant – daily and intolerable	<input type="checkbox"/> a. (lower GR) <input type="checkbox"/> b. (upper MD) <input type="checkbox"/> c. (lower MD)
7c. Does the level of disruption or strain represent a change in respect to pre-brain injury situation?	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Return to normal life</b>	
8a. Are there any other current problems relating to the injury which affect daily life?	<input type="checkbox"/> Yes (lower GR) <input type="checkbox"/> No (upper GR)
8b. If similar problems were present before the injury, have these become markedly worse?	<input type="checkbox"/> Yes <input type="checkbox"/> No
9. What is the most important factor in outcome?	<input type="checkbox"/> a. Effects of brain injury <input type="checkbox"/> b. Effects of illness or injury to another part of the body <input type="checkbox"/> c. A mixture of these
<b>GOSe Score</b>	

Version Date: March 4, 2021

**ACT-TBI-CRF****Long-term Follow-Up**

Patient ID: \_\_\_\_ - \_\_\_\_

<b>B. modified Rankin Scale (mRS)</b>	
Date of evaluation (DD/MMM/YYYY):	____ / ____ / ____
Respondent:	<input type="checkbox"/> Patient <input type="checkbox"/> Spouse <input type="checkbox"/> Son <input type="checkbox"/> Daughter <input type="checkbox"/> Father <input type="checkbox"/> Mother <input type="checkbox"/> Physical therapist <input type="checkbox"/> Speech therapist <input type="checkbox"/> Medical record <input type="checkbox"/> Other individual, specify role: _____ <input type="checkbox"/> Sister <input type="checkbox"/> Brother <input type="checkbox"/> Other relative, specify relationship: _____ <input type="checkbox"/> Friend <input type="checkbox"/> Nurse <input type="checkbox"/> Home health aide <input type="checkbox"/> Occupational therapist <input type="checkbox"/> Physician
<b>5 BEDRIDDEN</b>	
5.1 Is the person bedridden?	<input type="checkbox"/> Yes <input type="checkbox"/> No (5)
<b>4 ASSISTANCE TO WALK</b>	
4.1 Is another person's assistance essential for walking?	<input type="checkbox"/> Yes <input type="checkbox"/> No (4)
<b>3 ASSISTANCE TO LOOK AFTER OWN AFFAIRS</b>	
3.1 Is assistance ABSOLUTELY essential for preparing a simple meal?	<input type="checkbox"/> Yes <input type="checkbox"/> No (3)
3.2 Is assistance ABSOLUTELY essential for basic household chores?	<input type="checkbox"/> Yes <input type="checkbox"/> No (3)
3.3 Is assistance ABSOLUTELY essential for looking after household expenses?	<input type="checkbox"/> Yes <input type="checkbox"/> No (3)
3.4 Is assistance ABSOLUTELY essential for local travel?	<input type="checkbox"/> Yes <input type="checkbox"/> No (3)
3.5 Is assistance ABSOLUTELY essential for local shopping?	<input type="checkbox"/> Yes <input type="checkbox"/> No (3)
<b>2 USUAL DUTIES AND ACTIVITIES</b>	
<b>Work</b>	
2.1 Has the brain injury substantially reduced (compared to preinjury status) the person's ability to work (or, for a	<input type="checkbox"/> Yes <input type="checkbox"/> No (2)

Version Date: March 4, 2021

**ACT-TBI-CRF****Long-term Follow-Up**

Patient ID: \_\_\_\_ - \_\_\_\_

student, study)?	
<b>Family responsibilities</b> 2.2 Has the brain injury substantially reduced (compared to preinjury status) the person's ability to look after family at home?	<input type="checkbox"/> Yes <input type="checkbox"/> No (2)
<b>Social &amp; leisure activities</b> 2.3 Has the brain injury reduced (compared to preinjury status) the person's regular free-time activities by more than one half as often?	<input type="checkbox"/> Yes <input type="checkbox"/> No (2)
<b>Other physical/medical condition</b> 2.4 Are the patient's work, family, and/or social/leisure activities substantially reduced by a physical/medical condition other than the brain injury that led to trial enrollment?	<input type="checkbox"/> Yes <input type="checkbox"/> No (2)
<b>1 SYMPTOMS AS A RESULT OF THE BRAIN INJURY</b>	
<b>1.1 Spontaneously Reported Symptoms</b> 1.1 Does the patient have any symptoms resulting from the brain injury?	<input type="checkbox"/> Yes <input type="checkbox"/> No (1)
<b>1.2 Symptom Checklist</b>	
1.2.1 Does the person have difficulty reading or writing as a result of the brain injury?	<input type="checkbox"/> Yes <input type="checkbox"/> No (1)
1.2.2 Does the person have difficulty speaking or finding the right word as a result of the brain injury?	<input type="checkbox"/> Yes <input type="checkbox"/> No (1)
1.2.3 Does the person have problems with balance or coordination as a result of the brain injury?	<input type="checkbox"/> Yes <input type="checkbox"/> No (1)
1.2.4 Does the person have visual problems as a result of the brain injury?	<input type="checkbox"/> Yes <input type="checkbox"/> No (1)
1.2.5 Does the person have numbness (face, arms, legs, hands, feet) as a result of the brain injury?	<input type="checkbox"/> Yes <input type="checkbox"/> No (1)
1.2.6 Does the person have weakness or loss of movement (face, arms, legs, hands, feet) as a result of the brain injury?	<input type="checkbox"/> Yes <input type="checkbox"/> No (1)
1.2.7 Does the person have difficulty with swallowing as a result of the brain injury?	<input type="checkbox"/> Yes <input type="checkbox"/> No (1)
1.2.8 Does the person have any other symptoms related to the brain injury?	<input type="checkbox"/> Yes <input type="checkbox"/> No (1)
<b>Rankin Grade</b>	_____

Version Date: March 4, 2021

**ACT-TBI-CRF****Violations/Deviations**

Patient ID: \_\_\_\_ - \_\_\_\_

**8. Violations/Deviations**

1. Has there been any violations/deviations during the study?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If Yes, complete the following questions:	
Date/time occurred	____ / ____ / 20____ : ____
Specify violation	<u>Violations:</u> <input type="checkbox"/> Consent not obtained in 7 days. <input type="checkbox"/> Other (specify): _____
Provide the reason and all important information regarding the violation/deviation	_____ _____ _____

Version Date: March 4, 2021

**ACT-TBI-CRF****Final Protocol Disposition**

Patient ID: \_\_\_\_ - \_\_\_\_

**9. Final Protocol Disposition**

<b>1. How did the patient complete the study?</b>	
<input type="checkbox"/> Normal protocol completion <input type="checkbox"/> Protocol completion with protocol deviation <input type="checkbox"/> Study not completed <input type="checkbox"/> Withdrawal of consent <ol style="list-style-type: none"> <li>i. Date/time of withdrawal: ____ / ____ / 20____ : ____</li> <li>ii. Reason given: _____</li> <li>iii. <input type="checkbox"/> with authorization to use data <input type="checkbox"/> without authorization to use data</li> </ol>	
<b>2. Research Coordinator Signature</b>	
Signature: _____	Date (DD/MMM/YYYY): : ____ / ____ / 20____
<b>3. Investigator Signature</b>	
Signature: _____	Date (DD/MMM/YYYY): : ____ / ____ / 20____

Version Date: March 4, 2021

**ACT-TBI-CRF Summary of Radiology Tests** Patient ID: \_\_\_\_ - \_\_\_\_**1. Summary of Radiology Tests**

1. Radiology CRF		
1.1 Modalities available	CT Head	<input type="checkbox"/> Yes <input type="checkbox"/> No
	CTP	<input type="checkbox"/> Yes <input type="checkbox"/> No
	CTA	<input type="checkbox"/> Yes <input type="checkbox"/> No
1.2 Additional Ancillary Imaging Tests	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	<input type="checkbox"/> CT-scan angiography <input type="checkbox"/> MRI <input type="checkbox"/> MRI angiography <input type="checkbox"/> EEG <input type="checkbox"/> Transcranial Doppler <input type="checkbox"/> SSEP <input type="checkbox"/> Brain CT-perfusion (other than study's CT-perfusion) <input type="checkbox"/> Nuclear imaging (SPECT) <input type="checkbox"/> Other. Specify: _____ Remarks on this test: _____ _____ _____ _____	
1.3 Any other remarks		

Version Date: October 2, 2020

**ACT-TBI-CRF Summary of Radiology Tests** Patient ID: \_\_\_\_ - \_\_\_\_**2. Radiology Case Report Form: Plain CT Head****Instructions**

Please interpret plain CT head, when available. Base of skull fracture is to be commented upon.

If the potential cause of brain injury is not specified, please put that in Section 2.7.

If any other relevant findings on plain CT regarding potential diagnosis of brain death, please add that in remarks (Section 2.8).

Version Date: March 4, 2021



**ACT-TBI-CRF Summary of Radiology Tests** Patient ID: \_\_\_\_ - \_\_\_\_

<b>2. Plain CT Head: complete this section if Yes checked for CT Head</b>	
2.1. Date of interpretation	____/____/____
2.2. Plain CT Test ID:	_____
2.3. Diffuse loss of Grey-white differentiation compatible with diffuse cerebral edema	<input type="checkbox"/> Yes <input type="checkbox"/> No
2.4. Evidence of brain herniation	<input type="checkbox"/> Yes <input type="checkbox"/> No
2.5. Potential cause of brain injury on imaging:	_____
2.6. Subarachnoid hemorrhage,	<input type="checkbox"/> Yes <input type="checkbox"/> No
2.7. Intracranial hemorrhage	<input type="checkbox"/> Yes <input type="checkbox"/> No
2.8. Penetrating injury	<input type="checkbox"/> Yes <input type="checkbox"/> No
2.9. Large ischemic stroke (> 50% of the arterial territory)	<input type="checkbox"/> Yes <input type="checkbox"/> No
2.10. If other, specify	_____
2.11. Base of skull fracture	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Uncertain (bone window not available)
2.12. Remarks (any other findings)	_____

Version Date: March 4, 2021

**ACT-TBI-CRF Summary of Radiology Tests** Patient ID: \_\_\_\_ - \_\_\_\_**3. Radiology Case Report Form: CT Perfusion****Instructions**

**CTP definitions:** Both **qualitative and quantitative** assessment of CTP will be done.

**Qualitative assessment-** CTP images will be **qualitatively** assessed by 2 Neuroradiologists.

- Matched Cerebral Blood Flow (CBF) and Cerebral Blood Volume (CBV) defect will be defined as decrease in CBV and marked decrease in CBF in the brain **consistent with established infarct**.
- Brainstem matched CBF & CBV defect will be defined as a decrease in CBV and marked decrease in CBF in the whole cross-section of the brainstem in at least 2 consecutive 5 mm slices.
- Isolated Brainstem matched CBF & CBV defect will be defined as decrease in CBV and marked decrease in CBF in the whole cross-section of the brainstem (either midbrain, mid-pons or upper medulla level), but preserved CBF and CBV in rest of the brain parenchyma.

**Quantitative assessment-** will be done by a research associate under the guidance of Neuroradiologist (JS). Qualitative assessment of CTP will be done by putting a large region of interest incorporating the entire cross-section of the brainstem in the area of matched CBF and CBV defect. The absolute values of CBF and CBV will be obtained at midbrain, mid-pons and upper medulla level. The final values will be taken as average from the two slices. A CBF of <20mL/100g/min and/or a CBV of < 2 mL/100g will be considered compatible with irreversible brain damage and hence brainstem death.

In patients with no imaging evidence of brain death same method of measurement of absolute values of CBF and CBV of brainstem will be used. The values will be recorded as an average of CBF and CBV obtained at midbrain, mid-pons and upper medulla level.

Version Date: March 4, 2021

**ACT-TBI-CRF Summary of Radiology Tests** Patient ID: \_\_\_\_ - \_\_\_\_

<b>4. CT-Perfusion (CTP): complete this section if Yes checked for CTP</b>	
4.1. Date of interpretation	____ / ____ / ____
4.2. CTP Test ID:	_____
4.3. Contrast opacification in extra-cranial vessels	<input type="checkbox"/> Appearance <input type="checkbox"/> Disappearance
4.4. Whole brain matched CBF & CBV defect	<input type="checkbox"/> Yes <input type="checkbox"/> No
4.5. Brainstem matched CBF & CBV defect	<input type="checkbox"/> Yes <input type="checkbox"/> No
4.6. Isolated Brainstem matched CBF & CBV defect	<input type="checkbox"/> Yes <input type="checkbox"/> No
4.7. CBF at midbrain (cerebral peduncle level) (in ml/100 gm/min)	_____ ml/100 gm/min (Normal range 38-51)
4.8. CBV at midbrain (cerebral peduncle level) (in ml/100 gm)	_____ ml/100 gm (Normal range 3.1-4.5)
4.9. CBF at mid-pons (in ml/100 gm/min)	_____ ml/100 gm/min
4.10. CBV at mid-pons (in ml/100 gm)	_____ ml/100 gm
4.11. CBF at medulla (upper medulla level) (in ml/100 gm/min)	_____ ml/100 gm/min
4.12. CBV at medulla (upper medulla level) (in ml/100 gm)	_____ ml/100 gm
4.13. If isolated brain stem defect, describe the location of preserved perfusion (e.g., cerebral hemisphere, cerebellum or both)	<input type="checkbox"/> Cerebral hemisphere <input type="checkbox"/> Cerebellum <input type="checkbox"/> Both
4.14. Remarks	_____

Version Date: March 4, 2021

**ACT-TBI-CRF Summary of Radiology Tests** Patient ID: \_\_\_\_ - \_\_\_\_**5. Radiology Case Report Form: CT-Angiogram (CTA)****Instructions**

**CTA definitions:** The contrast opacification of the different segments of the intracranial vessels will be analyzed by 2 Neuroradiologists. CTA will be analyzed on a 4-point, 7-point and 10-point scales on the basis of lack of opacification of the different segments of the intracranial vessels.

Lack of opacification of each of these segments gives one point resulting in “lack of opacification” scores of between 0 and 7.

4-point scale- included non-opacification of 4 vessels- cortical segments of the bilateral middle cerebral arteries (MCA) and the 2 internal cerebral veins (ICV).

7-point scale- included non-opacification in 7 vessels- bilateral M4 segment (cortical branches) of the MCA, bilateral A2 segment (pericallosal branches) of the anterior cerebral artery (ACA), bilateral ICV, and the VOG.

10-point scale- included non-opacification in 10 vessels- bilateral M4 segment (cortical branches) of the MCA, bilateral A2 segment (pericallosal branches) of the anterior cerebral artery (ACA), basilar artery, bilateral P2 segment of the posterior cerebral artery (PCA), bilateral ICV, and the VOG.

Brain death will be called on 4-point scale- when all the 4 vessels were non-opacified (i.e., the score of 4). A score less than 4 will be called “not brain dead”.

Brain death will be called on 7-point scale- when all the 7 vessels were non-opacified (i.e., the score of 7). A score less than 7 will be called “not brain dead”.

Brain death will be called on 10-point scale- when all the 10 vessels were non-opacified (i.e., the score of 10). A score less than 10 will be called “not brain dead”.

Version Date: March 4, 2021

**ACT-TBI-CRF Summary of Radiology Tests** Patient ID: \_\_\_\_ - \_\_\_\_

<b>6. CT-Angiogram (CTA) (Peak): Complete this section if Yes checked for CTA</b>			
6.1. Date of interpretation		___/___/___	
6.2. CTA Test ID:		_____	
6.3. CTA contrast opacification in <b>Peak Arterial phase</b>		Right	Left
	Extracranial	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Supraclinoid Internal Carotid Artery (ICA)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Middle Cerebral Artery (MCA) (M4 or cortical segments)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Anterior Cerebral Artery (ACA) (A2/3 segment)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Intracranial Vertebral Artery	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Basilar Artery	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	PCA-P2	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Internal Cerebral Vein (ICV)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
6.4. Brain Death on CTA	Vein of Galen (VOG)	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	4 point Scale (MCA & ICV)	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	7 point Scale (MCA, ACA, ICV & VOG)	<input type="checkbox"/> Yes <input type="checkbox"/> No	
6.5. Remarks	10 point Scale (MCA, ACA, BA, PCA-P2, ICV & VOG)	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Version Date: March 4, 2021

**ACT-TBI-CRF Summary of Radiology Tests** Patient ID: \_\_\_\_ - \_\_\_\_

<b>7. CT-Angiogram (CTA) (Last Phase): Complete this section if Yes checked for CTA</b>			
<b>7.1. CTA contrast opacification in <u>last phase (at 60 sec)</u></b>		<b>Right</b>	<b>Left</b>
	Extracranial	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Supraclinoid Internal Carotid Artery (ICA)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Middle Cerebral Artery (MCA) (M4 or cortical segments)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Anterior Cerebral Artery (ACA) (A2/3 segment)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Intracranial Vertebral Artery	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Basilar Artery	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	PCA-P2	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Internal Cerebral Vein (ICV)	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>7.2. Brain Death on CTA</b>	Vein of Galen (VOG)	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	4 point Scale (MCA & ICV)	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	7 point Scale (MCA, ACA, ICV & VOG)	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<b>7.3. Remarks</b>	10 point Scale (MCA, ACA, BA, PCA-P2, ICV & VOG)	<input type="checkbox"/> Yes <input type="checkbox"/> No	

Version Date: March 4, 2021