

# ENTRY FORM

PLEASE COMPLETE 1-16 BEFORE RANDOMISING THE PATIENT

## ABOUT YOUR HOSPITAL *(please ensure all information below is contained in the medical records)*

1. Country	
2. Hospital code <i>(in your Study File)</i>	

## ABOUT THE PATIENT

3. Patient's initials <i>(first name/last name)</i>		4. Patient hospital ID			
5. Age <i>(years – approximate if unknown)</i>		6. Sex <i>(circle)</i>	<table border="1"> <tr> <td>MALE</td> <td>FEMALE</td> </tr> </table>	MALE	FEMALE
MALE	FEMALE				

## ABOUT THE INJURY AND PATIENT'S CONDITION

7. Time since injury <i>(insert hours)</i>		<i>Best estimate from history</i>			
8. Systolic Blood Pressure		<i>mmHg (most recent measurement prior to randomisation)</i>			
9. Glasgow Coma Score (GCS) <i>(circle one response for each category)</i>  First measurement in hospital of GCS <i>(if unknown give value at randomisation)</i>	<b>9A—EYE OPENING</b>		<b>9B—MOTOR RESPONSE</b>	<b>9C—VERBAL RESPONSE</b>	<i>IF GCS MORE THAN 12 AND NO CT SCAN AVAILABLE – <b>DO NOT RANDOMISE</b></i>  <i>IF GCS MORE THAN 12, CT SCAN IS AVAILABLE AND INTRACRANIAL BLEEDING=YES – <b>RANDOMISE</b></i>
	4 SPONTANEOUS	6 OBEYS COMMANDS	5 ORIENTATED		
	3 TO SOUND	5 LOCALISING	4 CONFUSED SPEECH		
	2 TO PAIN	4 NORMAL FLEXION	3 WORDS		
	1 NONE	3 ABNORMAL FLEXION	2 SOUNDS		
	2 EXTENDING	1 NONE			
	1 NONE				
10. This GCS is <i>(circle one)</i>	BEFORE	AFTER	intubation/sedation		
11. Pupil reaction	BOTH REACT		ONE REACTS	NONE REACT	UNABLE TO ASSESS
12. Any significant extracranial bleeding?	YES	NO	<i>Patients with extracranial trauma who are likely to need an early blood transfusion in the view of the attending doctor after taking into account mechanism of injury, findings from secondary survey, physiology and response to fluid infusion – <b>DO NOT RANDOMISE</b></i>		
13. Any intracranial bleeding on CT scan (before randomisation)? <i>(circle one)</i>	YES	NO	NO CT SCAN AVAILABLE	<i>IF CT SCAN AVAILABLE AND INTRACRANIAL BLEEDING=NO – <b>DO NOT RANDOMISE</b></i>	
14. Location of intracranial haemorrhage on CT Scan <i>(circle one response for each line)</i>					
a) Epidural	YES	NO			
b) Subdural	YES	NO			
c) Subarachnoid	YES	NO			
d) Parenchymal	YES	NO			
e) Intraventricular	YES	NO			

## RANDOMISATION INFORMATION

*Eligible if adult, with TBI, no significant extracranial bleeding, within 8h of injury (GCS=12 or less, or any intracranial haemorrhage on CT scan)*

15. Eligible? <i>(circle)</i>	YES	Get the lowest available number treatment pack and follow instructions	NO	Do not randomise, record on screening log		
16. Consent process for entry used? <i>(circle)</i>	WAIVER		OTHER REPRESENTATIVE		RELATIVE	
17. Insert treatment pack number here	<b>BOX</b>				<b>PACK</b>	
18. Date of randomisation	day	month	year	19. Time of randomisation <i>(24-hour clock)</i>	hours	minutes
20. Name of person randomising				21. Signature		

**SEE GUIDANCE OVERLEAF**

## **DATA FORMS GUIDANCE**

**AFTER COMPLETING THIS PAPER FORM PLEASE SEND THE DATA BY ANY METHOD LISTED:**

- ❖ Enter these data directly into the trial database (username and password required)
- ❖ Upload as a secure scanned document (see Study File for details)
- ❖ Fax to +44 20 7299 4663

**PLEASE STORE THE ORIGINAL FORM IN THE INVESTIGATOR'S STUDY FILE**

**PLEASE GIVE A COPY OF THIS COMPLETED FORM TO THE PERSON RESPONSIBLE FOR COMPLETING THE OUTCOME FORM AT YOUR HOSPITAL.**

**FOR UNBLINDING, ADVICE ON SERIOUS ADVERSE EVENT  
REPORTING AND OTHER URGENT ENQUIRIES PLEASE  
TELEPHONE **+44(0)7768 707500****