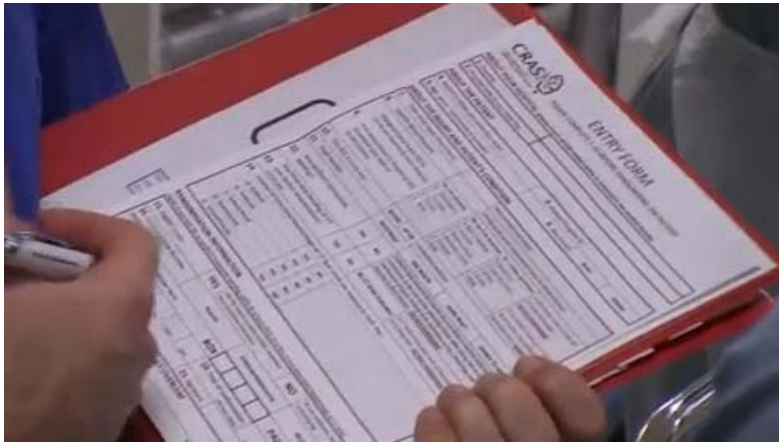
Completing the entry form

Protocol Code: ISRCTN15088122
V 1.1 date 12 Dec 2016

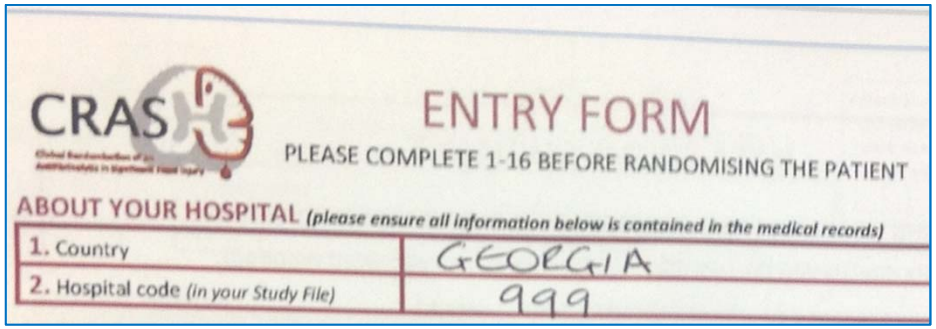
How to complete the entry form



- Use a paper entry form to capture the entry information
- Ensure information is recorded in the medical records – a label is provided for this purpose
- Forms are sent with the drug box, spare copies in Study File section 14 and on CD, also on trial website
- Please use permanent ink
- Questions 1–15 must be completed to assess eligibility before starting the consent procedure
- When consent procedure completed fill in the remaining fields

ALL fields must be completed for all randomised patients.

Sections 1–2 About your hospital



CRASH-3

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	GEORGIA
2. Hospital code *(in your Study File)*	999

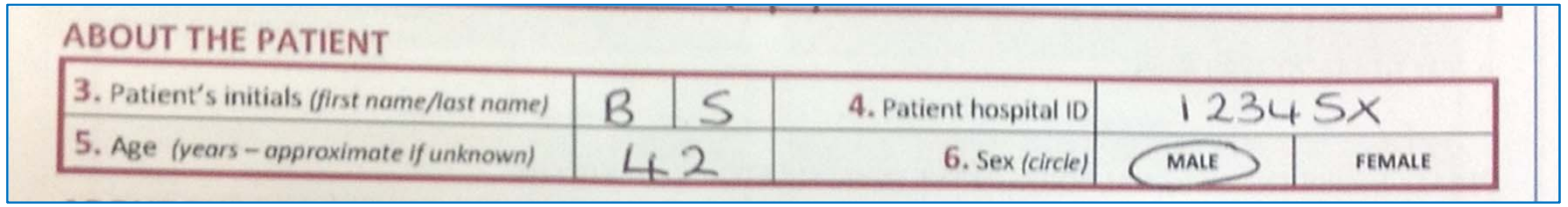
1. Country

- Write the name of your country in full

2. Hospital Code

- Enter the ID code for your site – the 3-digit number on the contact page of your Study File

Sections 3–6 About the patient



ABOUT THE PATIENT

3. Patient's initials *(first name/last name)*	B	S	4. Patient hospital ID	1234SX	
5. Age *(years – approximate if unknown)*	42		6. Sex *(circle)*	MALE	FEMALE

3. Patient initials

- Enter the patient's initials in the format FIRST name and LAST name
  eg Bilbo Frodo Samwell = **BS**
- If only one name is known enter that initial only
- If name is unknown because the patient has not been identified, use your hospital standard procedure (eg NK = not known)

4. Patient hospital ID

- Enter the number assigned to the patient by your hospital if allowed, otherwise insert the randomisation number

5. Age

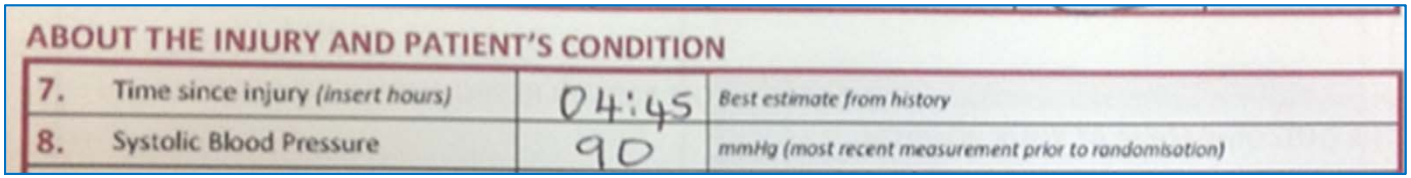
- Enter age in years
- If unknown, please enter *approximate* age in years

DO NOT RANDOMISE IF PATIENT DOES NOT MEET THE ADULT AGE REQUIREMENT FOR YOUR COUNTRY

6. Sex

- Specify if patient is MALE or FEMALE

Sections 7–8 The injury and patient's condition



ABOUT THE INJURY AND PATIENT'S CONDITION			
7.	Time since injury *(insert hours)*	04:45	*Best estimate from history*
8.	Systolic Blood Pressure	90	*mmHg (most recent measurement prior to randomisation)*

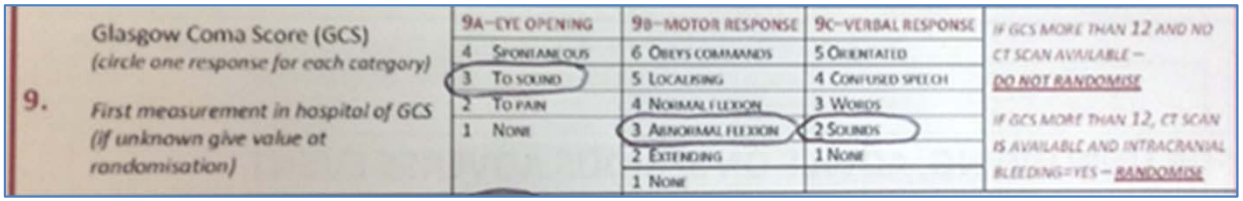
7. Time since injury

- Please provide the best estimate in hours from patient's history
- In hours eg 4¾ = 04:45 and ½ = 00:30
- If greater than 8 hours (for the remainder of the trial we will limit recruitment to patients who are within 3 hours of injury), patient is not eligible and should not be randomised

8. Systolic Blood Pressure

- Provide most recent measurement prior to randomisation in mmHg
- Enter a nominal value of '1' if unrecordable or '000' if value is missing – any missing value will require an explanation

Section 9 The injury and patient's condition



9. Glasgow Coma Score (GCS) *(circle one response for each category)* *First measurement in hospital of GCS (if unknown give value at randomisation)*	9A–EYE OPENING	9B–MOTOR RESPONSE	9C–VERBAL RESPONSE	IF GCS MORE THAN 12 AND NO CT SCAN AVAILABLE – DO NOT RANDOMISE IF GCS MORE THAN 12, CT SCAN IS AVAILABLE AND INTRACRANIAL BLEEDING=YES – RANDOMISE
	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		

9. Glasgow Coma Score (GCS)

- Ideally, record the measurement done before initiation of intubation or other resuscitative measures. Otherwise, use the measurement obtained just before randomisation.
- If GCS is more than 12 and there is no CT scan available, do not randomise.
- If GCS is more than 12 but there is CT scan with evidence of intracranial bleeding, patient may be randomised.
- If CT scan is available and shows no evidence of intracranial bleeding, do not randomise.

Sections 10–11 The injury and patient's condition

10.	This GCS is *(circle one)*	BEFORE	AFTER	intubation/sedation	
11.	Pupil reaction	BOTH REACT	ONE REACTS	NONE REACT	UNABLE TO ASSESS

10. GCS measurement

- Please record if the recorded GCS was taken before or after intubation/sedation

11. Pupil reaction

- Record at the same time as the GCS
- Every effort should be made to assess pupil reactivity
- 'Unable to assess' should only be used when it is physically impossible to assess (eg extensive facial trauma impacting the eyes)

Dilated pupil

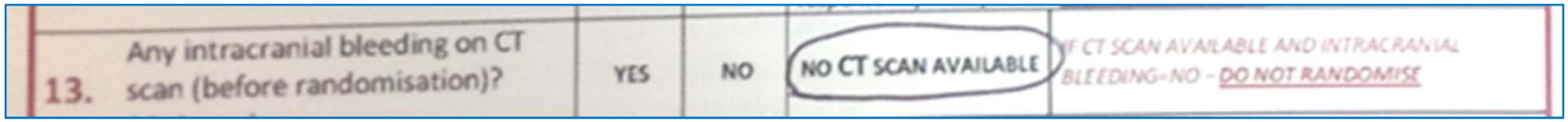
Section 12 The injury and patient's condition

12.	Any significant extracranial bleeding?	YES	NO	*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 – DO NOT RANDOMISE*

12. Significant extra cranial bleeding?

- If patient has significant extra cranial bleeding that in the opinion of the attending doctor is likely to require an immediate blood transfusion, they should NOT be randomised.
- The CRASH-2 trial showed that tranexamic acid improves outcomes in patients with or at risk of significant extra cranial bleeding. Therefore these patients should receive tranexamic acid and they should not be randomised.

Section 13 The injury and patient's condition



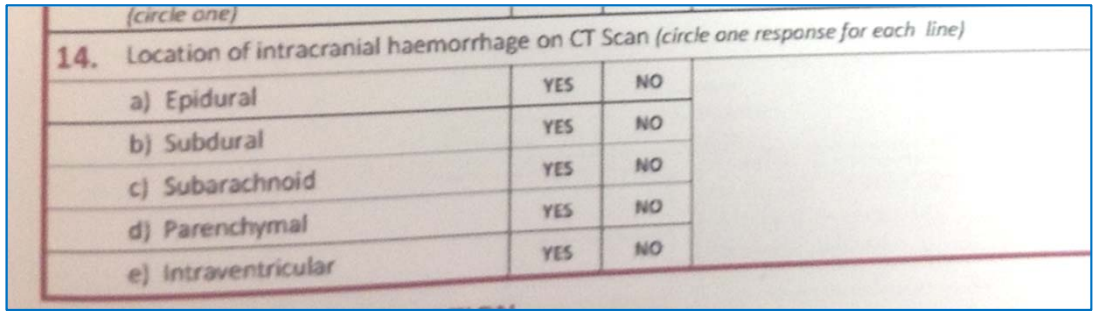
13.	Any intracranial bleeding on CT scan (before randomisation)?	YES	NO	NO CT SCAN AVAILABLE	IF CT SCAN AVAILABLE AND INTRACRANIAL BLEEDING=NO – DO NOT RANDOMISE

13. Intracranial bleeding on CT scan?

- Please indicate **Yes**, **No** or **No CT scan available**
- Scan should take place prior to randomisation
- If CT scan available and NO BLEEDING – DO NOT RANDOMISE
- If CT scan available and ANY BLEEDING present – RANDOMISE
- Attending doctor should take into account mechanism of injury, findings from medical examination, physiology and response to fluid infusion
- If CT scan is not available prior to randomisation but patient is eligible on GCS criteria and randomised, then a subsequent CT scan shows no bleeding, patient may remain in the trial

IF PATIENT HAS BEEN RANDOMISED IN ERROR PLEASE COMPLETE AND SUBMIT DATA

Section 14 The injury and patient's condition



(circle one)

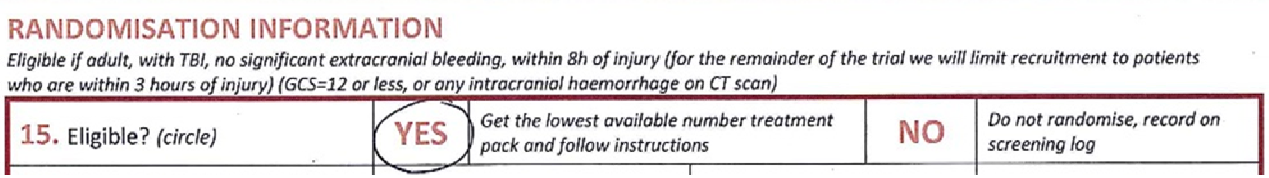
14. Location of intracranial haemorrhage on CT Scan *(circle one response for each line)*		
a) Epidural	YES	NO
b) Subdural	YES	NO
c) Subarachnoid	YES	NO
d) Parenchymal	YES	NO
e) Intraventricular	YES	NO

14. Location of Intracranial bleeding on CT scan

- If 'NO CT scan available' has been selected at Q13, leave Q14 blank and proceed to Q15

- Please indicate **YES** or **NO** for EACH line

Section 15 Randomisation



RANDOMISATION INFORMATION

Eligible if adult, with TBI, no significant extracranial bleeding, within 8h of injury (for the remainder of the trial we will limit recruitment to patients who are within 3 hours of injury) (GCS=12 or less, or any intracranial haemorrhage on CT scan)

15. Eligible? *(circle)*	YES	*Get the lowest available number treatment pack and follow instructions*	NO	*Do not randomise, record on screening log*

15. Eligible?

- Adult with TBI
- No significant extra cranial bleeding
- Within 8 hours of injury (for the remainder of the trial we will limit recruitment to patients who are within 3 hours of injury)
- GCS 12 or less OR any intracranial bleeding on CT scan

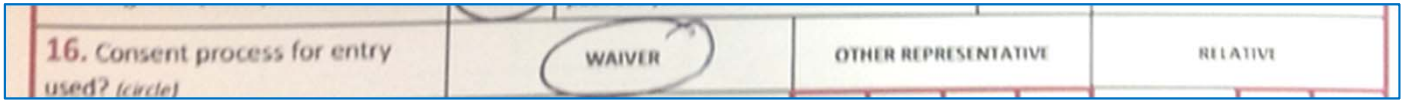
YES – patient fulfils all the above eligibility criteria and consent process has been followed

- **RANDOMISE** – get lowest available numbered treatment pack and follow instructions on it
- Record on Randomisation Log and Drug Accountability Log
- Submit entry form data to TCC within 24 hours

NO – patient does not fulfil all eligibility criteria

- **DO NOT RANDOMISE**
- Record on Screening Log
- If entry form used to assess eligibility, file in Study file Section 14

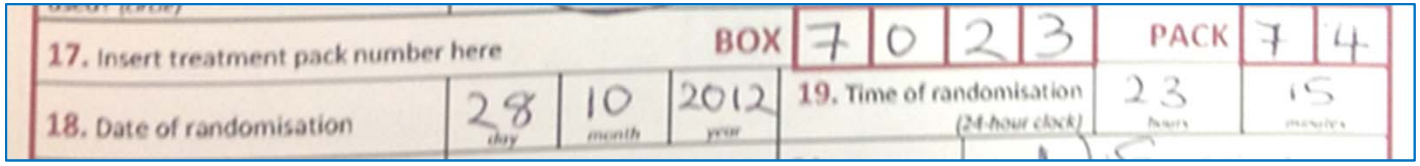
Section 16 Consent process



16. Consent process PRIOR to randomisation

- Please indicate if patient was entered in the study with agreement of representative/relative OR waiver of prior consent – circle one choice only.
- **NOTE: if relative AGREEMENT is given – this is recorded as a WAIVER**
- Only record the consent process used prior to randomisation, ie do not record in this section the follow-up consent procedure after the emergency is over.

Sections 17–19 Randomisation details



17. Treatment pack number

- Please write the box (4 digits) and pack (2 digits) number from the treatment pack

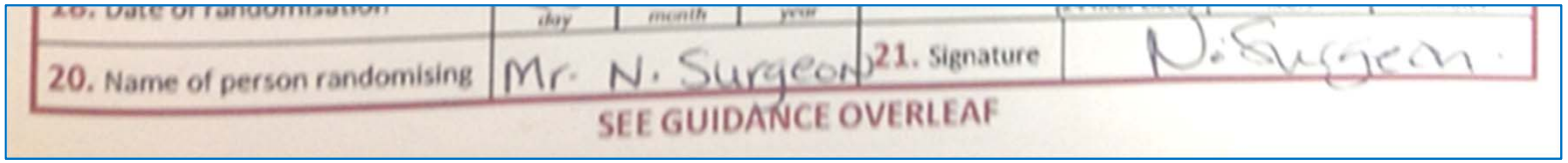
18. Date of randomisation

- Enter in format day (DD) month (MM) year (YYYY)

19. Time of randomisation

- Enter in format hours (HH) minutes (MM)
- Use 24-hour clock format eg 6pm = 18:00
- Midnight is designated as 00:00 of the following day
  eg randomised on 24/01/2012 at midnight = 25/01/2012 at 00:00

Sections 20–21 Randomisation declaration



20. Name of person randomising

- Write your name in full – print clearly

21. Signature

- Please sign the form – this is important as it validates the data on the form

How to make corrections

If you enter an incorrect value on the form:

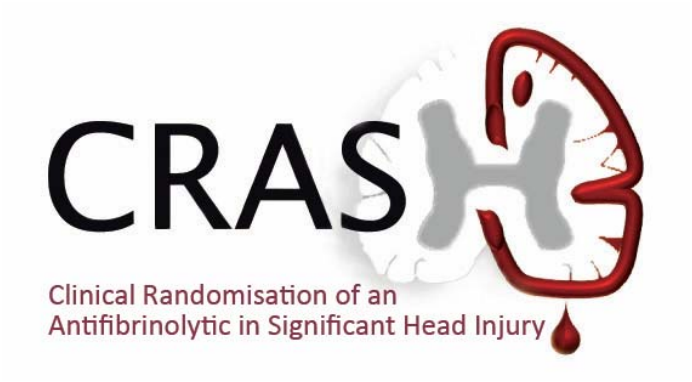
- cross out the incorrect value so it is still visible
- enter the correct value alongside
- date and initial **each** change

14. Location of intracranial haemorrhage on CT Scan *(circle one response for each line)*			
a) Epidural	YES	NO	
b) Subdural	YES	NO	
c) Subarachnoid	YES	NO	
d) Parenchymal	YES	NO	NS 24/10/2012
e) Intraventricular	~~YES~~	NO	

Please store original forms in Study file Section 14

SEE SEPARATE GUIDANCE ON HOW TO SEND DATA TO THE TCC

- Give a copy of the completed entry forms to the person responsible for completing the outcome forms at your hospital



Trial Coordinating Centre
London School of Hygiene & Tropical Medicine
Room 180, Keppel Street, London WC1E 7HT
Tel +44(0)20 7299 4684 | Fax +44(0)20 7299 4663
crash@Lshtm.ac.uk

crash3.Lshtm.ac.uk