HOW TO COMPLETE THE OUTCOME FORM

THIS FORM MUST BE COMPLETED FOR EACH PATIENT AT:

- **DISCHARGE** from the randomising hospital (for example to another hospital or home)
- **DEATH IN HOSPITAL** or
- **28 DAYS AFTER INJURY (NOTE - DAY 1 IS THE DAY FOLLOWING RANDOMISATION)**

WHICHEVER OCCURS FIRST

1. HOSPITAL

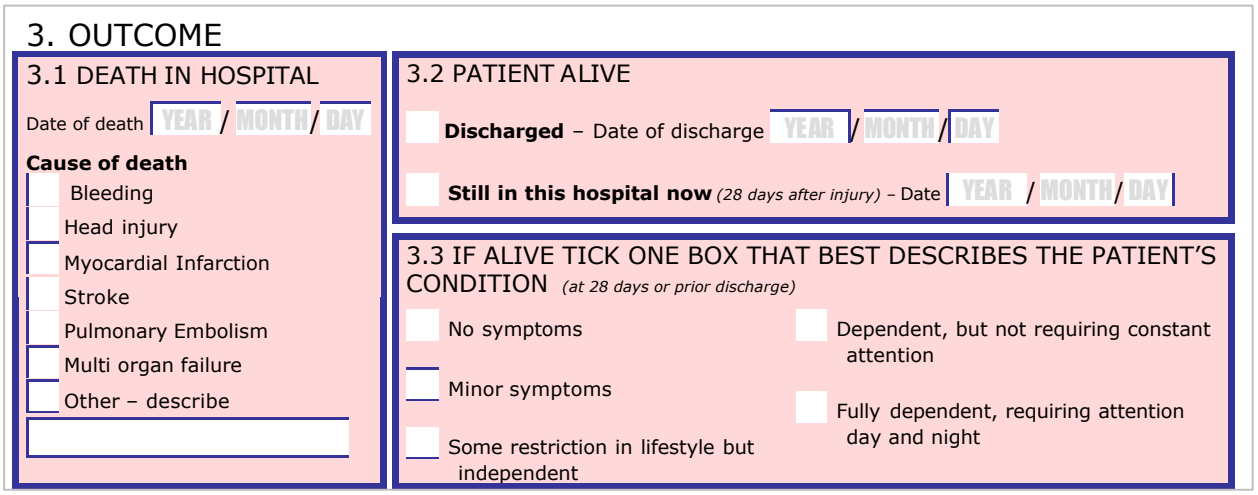
Name of the hospital where the patient is randomised **OR code number** allocated to your hospital by the Co-ordinating Centre – this can be found in your CRASH2 Trial Site File

2. PATIENT

Please record Patient Initials, Hospital ID Number, Sex and Date of Birth

PLEASE NOTE FORMAT YEAR/MONTH/DAY

3. OUTCOME



3.1 Death in hospital: If patient is alive when outcome is recorded – leave blank

a) Date of death: If patient dies in hospital **ON OR BEFORE** 28 days, please enter date of death (e.g. **2005 Feb 29**). Months should be entered as Jan, Feb, Mar, Apr, May, Jun, Jul, Aug, Sep, Oct, Nov, Dec. **[Note – Day 1 is the day following randomisation, i.e. randomised on 1st June = outcome due 29th June].**

b) Cause of death: Use post-mortem report if available to indicate cause(s) of death. Otherwise, please indicate the cause(s) of death recorded in patient's medical records.

3.2 If patient is dead leave blank. If Patient Alive: Enter the appropriate date in the format, e.g. **2005 Feb 29**

3.3 Patient's Condition: Only **ONE** condition applies – please tick the box that best describes the patient's condition at 28 days or prior discharge

4. MANAGEMENT

a) **Days in Intensive Care Unit** *(if not admitted to ICU, write '0' here)*		
b) **Significant Head Injury**	YES	NO
c) **Operation site -** *Tick one box on every line*		
• Neurosurgical	YES	NO
• Chest	YES	NO
• Abdomen	YES	NO
• Pelvis	YES	NO

a) Days in intensive care: Enter the number of days in the box and if the patient was **not** admitted to ICU put 0 (zero)

b) Significant Head Injury: Evidence of brain injury on CT scan. If no CT scan results are available – clinical evidence of brain injury such as a combination of decreased level of consciousness and clinical evidence of head injury.

c) Operation site: Please tick one box on each line. For example, if the only site was **Chest** tick **Yes** and for Neurosurgical, Abdomen and Pelvis please tick **No**.

5. COMPLICATIONS

Tick one box on every line		
• Pulmonary Embolism	YES	NO
• Deep Vein Thrombosis	YES	NO
• Stroke	YES	NO
• Operation for bleeding	YES	NO
• Myocardial Infarction	YES	NO
• Gastrointestinal bleeding	YES	NO

Please answer each question:
One box on each row must be ticked to indicate the presence or absence of that particular complication.

Tick '**YES**' only if there is a definite clinical diagnosis of a complication. Do **NOT** tick yes if there is only a suspicion of a complication.

6. TRIAL TREATMENT

a) Complete **loading dose** given	YES	NO
b) Complete **maintenance dose** given	YES	NO

a) Loading Dose: One box must be ticked.

b) Maintenance dose: Only tick **YES** if the complete maintenance dose was given. If anything less than complete or none at all, tick **NO**.

7. TRANSFUSION

a) Blood products transfusion	YES	NO
b) Units transfused in 28 days		
• Red cell products	units	
• Fresh frozen plasma	units	
• Platelets	units	
• Cryoprecipitate	units	
• Recombinant Factor VIIa	YES	NO

a) Blood products: Indicate whether the patient received any type of blood products (one box must be ticked).

b) Units transfused: Write the number of units the patient was exposed to e.g. if a patient received 2 and a half units of blood – please put 3 units. If patient received only **whole blood**, please put the number of units given under 'red cell products'.

Recombinant Factor VIIa: One box must be ticked

9. PERSON COMPLETING FORM

Please write your name clearly. Enter the position you hold and the date the form was completed. This information is important and will be used for audit purposes.

PLEASE PRINT A COPY OF THE OUTCOME FORM BEFORE SUBMITTING AND STORE IN YOUR HOSPITAL SITE FILE