

PATIENT UNABLE TO CONSENT

Patients in this trial are unable to consent for themselves due to impairment in their mental capacity caused by the traumatic brain injury

RELATIVE (IF AVAILABLE) IS GIVEN BRIEF INFORMATION – NOT EXPECTED TO PROVIDE VALID INFORMED WRITTEN CONSENT, ONLY AGREEMENT

If available, this sudden acute traumatic situation will have immense emotional and psychological effects on relatives – consider their ability for informed decision making. Treatment for their relative is required urgently. The nature of the trial also requires urgent action. It is not reasonable to expect relatives to provide valid, informed written consent in the critical emergency situation. They may be able to agree or disagree.

AGREEMENT GIVEN BY RELATIVE OR NO RELATIVE PRESENT

Two clinical personnel, one independent of the trial, decide to enrol the patient into the trial?

YES

RANDOMISE PATIENT

As soon as possible after the emergency is over **OR** patient regains competence, give full information and seek written consent from relative or patient for continuation in the trial.

NO

**DO NOT
RANDOMISE**